Michael D. Granston
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an interview by Gabriel L. Imperato

Meet Michael D. Granston

*This interview with Director **Granston** was conducted in July by SCCE & HCCA board member **Gabriel L. Imperato**, Esq. (gimperato@broadandcassel.com), Managing Partner, Fort Lauderdale office of Nelson Mullins Broad and Cassel LLP.*

GI: Please tell our readers about your background and how you became Director of the Civil Fraud Section of the Department of Justice (DOJ).

MG: Following law school and clerkships at both the district and appellate court levels, I worked as an associate at the Washington DC law firm Covington & Burling. At the firm, I had the opportunity to work on a diverse array of civil and criminal cases. These matters included both white-collar fraud investigations as well as a variety of healthcare issues, and the intersection of these areas of responsibility sparked my interest in healthcare fraud. Thus, in 1997, I took advantage of the opportunity to join the Civil Fraud Section of the Justice Department, due to its responsibility for bringing False Claims Act (FCA) cases and its growing focus on healthcare fraud enforcement. I had the subsequent good fortune to learn from a tremendous array of extremely talented and committed public servants, and in 2013, I became the director of the office. In that capacity, I have attempted to continue the Fraud Section's legacy of active but judicious enforcement of the FCA to protect taxpayer funds against fraud and abuse.

GI: I know that you have taken an active role in participating in the Health Care Compliance Association conferences and

have spoken about FCA enforcement and legal developments at the annual Compliance Institutes. Why is it important to you and the DOJ to participate in the HCCA conferences?

MG: I have always valued the opportunity to participate in HCCA events, because of the unique, and uniquely important, role played by the Association's members. To rid our healthcare system of fraud and abuse, we need to do more than just pursue fraud after it occurs. We need to stop it before it happens. The key to such a result is the efforts of those on the front lines who help ensure the day-to-day compliance of our nation's healthcare providers. The Association's events provide an important forum for Department attorneys to share their views and findings with these compliance professionals and, in turn, to hear the concerns and needs of those in the field. This type of exchange helps strengthen the relationship between DOJ attorneys and compliance professionals, which in turn enhances the ability of both groups to protect the integrity of our healthcare system.

GI: Explain to our readers the difference between when the DOJ declines to intervene in a case and the dismissal of the case. If DOJ has made a decision to decline a case, why not dismiss it instead?

MG: The number of whistleblower or *qui tam* suits has grown considerably since 1986, and the Department now routinely receives between 600 and 700 per year. As a result, the DOJ does not have the resources to pursue every meritorious *qui tam* case, and the fact that the DOJ declines to intervene in a case does not necessarily mean that it lacks merit. At the same time, the Department unquestionably does decline to pursue some *qui tam* cases due to the absence of any legal or factual support. In these latter circumstances, the DOJ will consider whether it should exercise the dismissal authority granted by Congress to advance the interests of the United States. As set forth in recent guidance issued by the DOJ, those interests may include avoiding the time and resources needed to monitor the case; the burden placed on government agencies of responding to discovery requests; the expense imposed on the defendant, which in some circumstances may be charged back by government contractors to the United States; and the risk that a meritless case may lead to bad case law.

GI: What has been the impact of the Supreme Court's decision in the *Escobar* case[1] in terms of the volume of cases or the decision to decline or dismiss a case?

MG: I don't know that we have a sufficient basis yet to make any quantitative assessment of the impact of the Supreme Court's decision in *Escobar* on the volume of cases being pursued. Given that *Escobar* addressed a number of issues related to falsity and materiality, one might expect the impact of the decision to be mixed, providing added support for some cases and removing the basis for other cases. The Department is, of course, taking the ruling in *Escobar* into account in evaluating the merits of the cases it investigates, in soliciting the views of the victim agencies, and in determining ultimately what cases to pursue, decline, or dismiss.

GI: Has the percentage of cases in which the Department has intervened changed over time? What about the percentage of cases the DOJ has litigated?

MG: Despite the increase over time in the number of *qui tam* filings by whistleblowers, the Department's historical intervention rate in those actions has remained relatively constant. Since 1986, when the False Claims Act's *qui tam* provisions were substantially amended, the Department has intervened in about 20% to 25% of the *qui tam* cases that are filed.

Since the Department does not track the number of False Claims Act cases that are litigated, I cannot give you a precise answer to the question of whether the percentage of litigated matters has increased. Certainly, the overall number of matters being litigated or going to trial has increased, but that may be a function in significant part of the overall increase in the number of FCA cases—both *qui tam* and non-*qui tam* matters—being pursued by the DOJ.

GI: What has been the impact of the Brand Memo, which prohibits the use of agency guidance documents as a basis for proving violations of applicable law in False Claims Act cases, on the DOJ's ability to prosecute False Claims Act cases?

MG: On January 25, 2018, the former Associate Attorney General, Rachel Brand, issued a memorandum on the use of agency guidance documents in affirmative civil enforcement cases. This memo, also known as the Brand Memo, serves as an important reminder to Department attorneys about the role that agency guidance should play in civil enforcement matters, including FCA cases. The Memo makes clear that agency guidance should not serve as the basis for imposing new legal obligations beyond those already encompassed by statute, regulation, or contract. At the same time, it recognizes that guidance may be used for other proper purposes, so long as those purposes do not result in the guidance inappropriately being given the force and effect of law. For example, in appropriate circumstances, the DOJ could use guidance as evidence of the defendant's awareness of an agency's interpretation of a particular legal requirement or the agency's views on the materiality of that requirement. However, even in such circumstances, the defendant may argue that the agency's interpretation is not binding and that a different interpretation of the applicable legal requirement is warranted.

GI: How would you describe the impact of False Claims Act cases on organizational compliance in the healthcare industry?

MG: I think there can be no argument that the prospect of FCA liability, coupled with the Act's incentives for insiders to disclose wrongdoing, has sharpened the focus of the healthcare community on compliance issues. Healthcare providers have come to realize that not only are strong compliance programs good for business by enhancing employees' awareness of their legal obligations, but they also promote internal reporting by giving potential whistleblowers a mechanism to voice their concerns. A common complaint we hear from those who file *qui tam* actions is that they tried to raise issues within their company but were rebuffed. The presence of a genuine and active compliance program is also something we will consider when evaluating whether a company knowingly violated the False Claims Act, or whether the conduct at issue was anomalous and the result of a simple mistake.

GI: How would you characterize the current DOJ's commitment to the enforcement of the False Claims Act?

MG: I have yet to meet any government official who thinks fraud is a good thing. New leadership often brings new ideas and new priorities. But, during my 20 years with the Department, ensuring that taxpayer funds are used appropriately and productively has always been a core objective, and it continues to be a significant focus of the Department. Indeed, the Acting Associate Attorney General recently affirmed that this administration is committed to pursuing "vigorous False Claims Act enforcement"

that is "fair and consistent with the rule of law."

GI: What do you see down the road related to enforcement of and liability under the False Claims Act in the healthcare industry? Does this change from administration to administration and, if so, what have been some of the differences from administration to administration?

MG: As I noted earlier, it is not unusual for new administrations to have new ideas and priorities, and the current administration has identified several healthcare enforcement objectives that are impacting the Department's use of the False Claims Act.

One of the administration's key healthcare priorities is to combat the prescription opioid crisis. Consistent with this objective, the Department is using all of its available criminal and civil remedies, including the False Claims Act, to redress the conduct of any entity in the opioid distribution chain—including pharmaceutical manufacturers, wholesale distributors, pharmacies, pain management clinics, drug testing laboratories, and physicians—that contributes to the abuse or diversion of opioids. In April, for example, the Department intervened in five whistleblower lawsuits filed under the False Claims Act against Insys, the manufacturer of an opioid product called Subsys, which is one of the most highly addictive opioid products available and is approved only for patients with cancer who are suffering from breakthrough pain. The DOJ has alleged in its complaint that Insys used a variety of illegal means to increase prescriptions of Subsys, including paying kickbacks and lying about patients having cancer.

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Consistent with another key administration priority, the Civil Division is using the FCA to pursue cases against drug manufacturers and others whose illegal conduct is contributing to rising drug prices. Last year, the DOJ settled with Mylan Pharmaceuticals, which drastically raised the price of its brand name drug EpiPen, while reporting the drug as a generic to the Medicaid program to avoid paying rebates triggered by its price increases. More recently, the Department has pursued FCA claims against drug manufacturers for using foundations as conduits to pay the copays of Medicare patients, and against pharmacies and others for using illegal means to induce prescriptions and to manipulate formulas to inflate reimbursements for compounded medications.

Yet another focus of the current administration is to protect seniors from elder fraud and abuse. As part of this commitment to elder justice, the DOJ is using the False Claims Act to protect seniors and federal healthcare programs in various ways, including pursuing nursing homes that provide and bill for grossly substandard care to their residents, therapy providers who are erroneously billing for medically unnecessary services, hospice companies that are admitting non-terminal patients who then lose their eligibility for curative care, and other healthcare providers that seek to take advantage of older Americans for their own gain.

GI: What is the relationship among the DOJ, the Centers for Medicare & Medicaid Services (CMS), Health and Human Services Office of the Inspector General (HHS OIG), and the state Medicaid programs? How does the DOJ work

with these three agencies in developing and prosecuting False Claims Act cases?

MG: The success of the Department's healthcare fraud enforcement efforts is due in no small part to the close relationship it has with its various partners in this area. Every *qui tam* case that is filed is sent not only to the Criminal Division, but also to the FBI and the pertinent agencies, such as CMS and HHS/OIG in Medicare and Medicaid matters. During the course of an investigation, in addition to the foregoing entities, we will also coordinate closely with HHS Office of the General Counsel (OGC) and the CMS Center for Program Integrity (CPI), as well as the state Medicaid agencies in cases implicating the Medicaid program. Our coordination encompasses not only a discussion of the applicable rules, but also the agencies' views of the particular allegations at issue and the most effective way to structure an investigative plan. At the end of our investigation, we will solicit a recommendation from the various agencies involved as to how the Department should proceed, and whether the DOJ should pursue an action under the FCA.

We also coordinate closely with our criminal colleagues with respect to False Claims Act matters. As I mentioned, every *qui tam* case is shared with the Criminal Division, and the Department frequently pursues parallel criminal and civil False Claims Act investigations. An important aspect of this coordination, as reinforced by a recent update to the *U.S. Attorneys' Manual*, is to ensure that any fines and penalties are not unnecessarily duplicative and that defendants are subject to an appropriate level of punishment. At the same time, the policy makes clear that Department attorneys are not precluded in appropriate circumstances from pursuing additional remedies, including remedies under the FCA, designed to compensate the government for its losses.

GI: What tips do you have for defense representatives (i.e., counsel and compliance professionals) related to their interaction with DOJ during a False Claims Act case?

MG: The two most important suggestions I can provide are to engage early and be forthright with the Department attorney handling the matter. The benefits of early communication are several fold. If your client or company has a valid explanation for the allegations under review, everyone benefits if that explanation is aired early in the process, before either side expends substantial time and resources on unnecessary investigative steps. By contrast, if a problem exists, then again the parties can benefit by exploring at the outset possible ways for your client to cooperate in the government's investigation and, potentially, ways to resolve the matter. As the Department has now made clear on various occasions, it welcomes and will reward corporate defendants that provide meaningful assistance in FCA investigations. The DOJ has tremendous enforcement discretion under the statute to structure settlements that provide a material discount based on a defendant's cooperation, while simultaneously ensuring that the government is made whole.

Being open and candid with the government's representative is equally important. It will help you gain credibility, which will serve you well later on, whether you are negotiating over the production of information or the appropriate resolution of the case. This does not mean you should not vigorously defend your client's interests. But if you assert frivolous arguments, fail to disclose key facts in presentations, or otherwise are not forthright, the Department attorney may become skeptical even of valid arguments or defenses, which may unduly prolong the pursuit of a matter.

GI: How important are relators/whistleblowers to the government? What role do

whistleblowers' attorneys play in the government's investigation or litigation of *qui tam* cases? Has that role changed over time?

MG: *Qui tam* suits continue to serve as a primary vehicle for the disclosure of healthcare and other fraud schemes involving taxpayer funds. Just last year, of the 815 new False Claims Act investigations opened by the Department, 680 were initiated by the filing of a *qui tam* action. Of these 680 suits, 495 involved allegations of healthcare fraud. And, as in years past, the bulk of the government's recoveries last year occurred in *qui tam* cases. Of the $3.4 billion recovered during fiscal year 2017, $3.1 billion was recovered in *qui tam* cases, including $2.1 billion in *qui tam* cases alleging healthcare fraud. Moreover, the numbers alone do not fully capture the impact of *qui tam* cases, which often bring to the government's attention allegations of complex corporate wrongdoing that are best understood and unearthed by insiders.

The success of this public-private partnership is due in part to the efforts of whistleblower attorneys. They have historically served an important role in helping whistleblowers bring their knowledge of wrongdoing to the government's attention, and have increasingly also helped supplement the government's own resources, particularly when it comes to litigating FCA matters in which the government has intervened. One additional way that whistleblower attorneys can help promote the success of the public-private partnership is to serve as active gatekeepers of the *qui tam* provisions by vigorously vetting the claims of putative whistleblowers and filing only those suits that are adequately supported by law and fact. Such assistance will enable the government to focus its resources on the most meritorious matters, including *qui tam* cases filed by whistleblowers.

1. *Universal Health Services Inc. v. United States et al. ex rel. Escobar et al.* October 2015. Available at http://bit.ly/2rC1abg