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False Claims Act Risk to Private Equity Healthcare Investors

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As many healthcare practitioners and attorneys can attest, private equity investment has become an increasingly prevalent feature of the healthcare industry. From blockbuster deals like KKR's purchase of Envision Healthcare Corp., to smaller but numerous physician practice buyouts by private equity firms across the country, the perceived benefits of private equity investment have proved alluring to healthcare providers. And from the opposite perspective, the expected profits of the healthcare industry — an industry responsible for nearly a fifth of U.S. gross domestic product (GDP) — have proved powerful attractions for private equity investors. Recent developments in government enforcement and the attention paid to private equity investors in healthcare, however, raise significant enforcement risks for private equity firms interested in healthcare. Three recent False Claims Act (FCA) cases demonstrate the increasing risk faced by private equity firms involved in healthcare investment and guideposts for mitigating that risk.

Private Equity Investment in Healthcare

The healthcare industry represents a diverse assortment of participants, including pharmaceutical companies, medical device manufacturers, healthcare technology businesses and various healthcare providers. Each area presents several attractive characteristics for private equity investors. From potentially high margins and growth potential for medical device manufacturers to operational efficiencies available through physician practice acquisition, the healthcare sector is full of opportunities for growth and favorable return on investment.

The potential gains from investment in the healthcare sector have spurred significant increases in investments over the last five years. From 2015 to 2019, the number of private equity deals increased by approximately 50 percent and deal value doubled from under $40 billion in 2015 to nearly $80 billion in 2019.[1]

Because healthcare is a highly regulated industry, numerous statutes, regulations and regulatory changes are relevant to private equity investors. Specific risks from fraud and abuse enforcement, however, have recently become more significant. Fraud and abuse against government programs not only can wipe out the value of portfolio companies, but can expose the private equity firm to direct liability under the federal FCA, state law equivalent statutes, and Health and Human Services' Office of Inspector General (OIG) exclusion authorities. Understanding the various risks associated with these enforcement regimes will prepare private equity investors to mitigate this risk and secure their investments.

Fraud and Abuse Risk Overview

The federal government is the single largest payor in the healthcare system through multiple government programs, including Medicare, Medicaid, TRICARE, and the Federal Employee Health Benefits Program. The government protects these programs from fraud and abuse through various measures, but the most important arrow in the quiver is the federal FCA.[2] On its own, or in combination with the Anti-Kickback Statute (AKS),[3] the Physician Self-Referral Law (the Stark Law)[4] and the Food Drug and Cosmetic Act (FDCA),[5] the FCA is a sledgehammer poised to wreak financial ruin on firms caught in its snare.

The FCA, known as the "Lincoln Law," is a Civil War-era statute passed to combat fraudulent sales of sub-standard equipment to the Union Army by war profiteers. For decades, the statute was used to force government contractors to repay treble the amount of damages they caused to the United States by their fraudulent sales. Amendments to the law over the years and aggressive application of the law by the Department of Justice (DOJ) have transformed the FCA into a devastating weapon to penalize companies the government believes to have cheated its healthcare programs. Of equal importance to government enthusiasm, however, is the proliferation of "whistleblower" suits that have driven the expansion of theories of liability under the FCA. Every year since 2007, far more money has been recovered in whistleblower lawsuits under the FCA than suits from non-whistleblower government investigations.[6]

If an entity is found to have violated the FCA – that is to knowingly submit a false claim to the United States – it is responsible for three times the amount the government paid the entity, plus penalties of approximately $11,000 to $23,000 per claim.[7] A claim can be considered false for a wide variety of reasons, including lack of medical necessity or failing to comply with any one of the vast number of regulations in the government health program systems.

Additionally, the FCA can be layered over violations of other anti-fraud statutes, such as the AKS Statute and the Stark Law, and paired with other regulatory regimes such as the FDCA. The government has successfully argued that violation of one of those statutes results in false claims because the claims are in effect tainted by the violation of the other statute. For example, a pharmaceutical company can be held criminally liable under the FDCA for marketing drugs for a use that is not approved by the Food and Drug Administration – commonly referred to as off-label marketing. The FCA, however, is used to hold the company financially liable for every claim for payment of the drug for the non-approved use. Some of the world's largest pharmaceutical companies have paid the United States billions in FCA settlements to resolve allegations of such activity.[8]

Large companies, however, are not the only targets of FCA suits. Even a single-practitioner office may submit thousands of claims to Medicare and Medicaid in just one year, leading to potentially ruinous liability for FCA violations. Damages and penalties under the FCA can reach mindboggling proportions, routinely exceeding $100 million in the largest cases. Over the past six years alone, the government has used the FCA to recover over $23.4 billion.[9]

In addition to the onerous liability provisions in the FCA, two other key components of the FCA make it a particularly ominous statute. First, liability can be based on a "reckless disregard" standard. This means that if the government determines that the entity may have submitted claims with "reckless disregard" for the truth or falsity of the claims, then the entity can be held liable. In practical effect, if the government determines an entity was simply not careful enough, that entity could potentially be on the hook for millions in damages. Often whistleblowers and the government take the position that healthcare companies are responsible for familiarity with the thousands of rules in the byzantine regulations that govern Medicare, Medicaid and other programs. Ignorance of the rules in a heavily regulated industry with sophisticated players may itself constitute reckless disregard. Thus, violation of any number of these rules may be a basis for FCA liability.

Another particularly vexing part of the FCA for healthcare entities is the whistleblower provision. Under the FCA, a whistleblower – referred to as a "relator" under the statute – may file a complaint in court on behalf of the United States. The relator, often an employee or former employee of the entity, very often accuses the provider of violating the FCA in the complaint. The government is then statutorily *required* to investigate the relator's allegations. If the government pursues the case and recovers money from the entity, the relator can receive up to 25 percent of the

government's recovery.[10] Perhaps most disturbingly for healthcare defendants, however, is that even if the government decides not to pursue the case after investigating the allegations, the relator can usually still sue the defendant on his or her own and obtain even a greater share of the recovery.[11] Whistleblowers are, therefore, powerfully incentivized to bring forth possible cases of fraud. Many relators have received millions of dollars in bounty payments from the government. For example, the relator in the high-profile Tuomey hospital system Stark Law case received $18.1 million after the DOJ settled the case post-judgment in 2015.[12] In 2009, six whistleblowers shared a $102 million bounty when Pfizer settled FCA claims with the United States.[13]And just recently, in September 2020 a relator was awarded $10 million when the DOJ settled Stark Law and AKS claims against Wheeling Hospital.[14]

False Claims Act and Private Equity Funds

Recent years have seen private equity backers of healthcare companies increasingly named in FCA cases. The reasons are twofold. First, the DOJ recently began to focus on holding *all* culpable parties liable in FCA cases as a means of deterring future illegal conduct.[15] This resulting focus of looking at all possible actors in an alleged healthcare fraud has meant that the government is increasingly looking at investors — including, in some cases, passive investors. Second, the government and whistleblowers are looking for all potentially responsible parties with resources to pay a settlement or judgment for FCA violations.

In 2015, Deputy Attorney General Sally Yates issued guidance — the apt-named "Yates Memo" — on individual accountability for corporate wrongdoing. The memorandum emphasized that deterring future wrongdoing required holding individual, rather than solely corporate, wrongdoers responsible. Though much attention on the memo focused on criminal prosecution and requirements for corporate cooperation, the memo made plain that FCA investigations should seek out all culpable persons and hold them accountable for damages to the United States. Shortly thereafter, Acting Associate Attorney General (AAAG) Bill Baer expanded on these concepts in the area of FCA cases, stating "[h]olding accountable the people that committed the wrongdoing is fundamental to ensuring that the public has continued confidence in our justice system."[16] Although the Yates Memo and AAAG Baer's comments focus on individuals, the concept for pursuing private equity firm owners of healthcare providers are the same. If the DOJ can find culpability for the portfolio company's conduct by private equity firm actors, it will pursue liability at both the private equity firm and those members of the firm at fault.

More practically, however, the private equity firm and its partners, principals or members are

often the only ones with money to satisfy an FCA judgment or pay a settlement. Government lawyers and investigators often dedicate years investigating FCA violations. After establishing that an entity has violated the FCA and caused substantial damage to federal healthcare programs, it is extremely frustrating to stare into a dry well. A responsible government enforcement lawyer will almost certainly investigate the entity that has benefited financially from the portfolio company's activities – which, increasingly often is a private equity firm. Additionally, it is not only DOJ lawyers and investigators a private equity firm must tangle with. Whistleblowers, with financial incentives absent from DOJ lawyers, will certainly name private equity firms backing healthcare operating companies in their lawsuits.

Three fairly recent cases demonstrate private equity funds in the crosshairs of FCA enforcement actions. Though in different stages of litigation, these cases provide lessons for private equity firms in evaluating and mitigating risks associated with healthcare investments. Importantly, these cases suggest that control and the involvement in management of the portfolio company, which may be essential to improved performance and increased value, may bring with it the risk for liability for violations of the FCA.

United States ex rel. Medrano and Lopez v. Diabetic Care RX, LLC Riordan Lewis & Hayden, Inc. Patrick Smith and Matthew Smith

The first, *United States ex rel. Medrano and Lopez v. Diabetic Care RX, LLC Riordan Lewis & Hayden, Inc. Patrick Smith and Matthew Smith*, in the Southern District of Florida marks the first time that the DOJ has extracted a settlement from a private equity firm investing in a healthcare provider. The Private Equity firm, Riordan, Lewis & Haden (RLH), agreed to pay the United States $21 million to resolve FCA liability for claims submitted by its compounding pharmacy portfolio company.[17]

The alleged facts in this case, in which the United States intervened, show perhaps the most direct involvement by the private equity firm in the actual alleged fraud of the operating company. RLH was a private equity investor in a pharmacy, Diabetic Care RX (DCRX). The government alleged that two partners of RLH served on the board of DCRX. RLH initiated DCRX's use of contracted sales representatives to purportedly peddle compounded pain creams to beneficiaries of TRICARE, the government health program for military personnel and their families. Additionally, RLH hired a new chief executive officer and carefully coordinated the compounding cream business plan with him. RLH partners on DCRX's board received regular reports, including revenues from compounding creams sales to federal programs and the allegedly illegal

commissions paid to marketers. The United States alleged that the marketing of these medically unnecessary pain creams through contracted sales representatives violated the AKS, making all claims to TRICARE for these products fraudulent.

RLH moved to dismiss the claims against it on the grounds, among others, that it lacked knowledge of the fraud. The magistrate's report and recommendation in the case found that the complaint sufficiently pled RLH's knowledge of the fraud.[18] Noting that in addition to being advised by counsel that paying commissions to marketers could violate the AKS and that violations of the AKS are material to reimbursement from TRICARE, the complaint also alleged that RLH:

1. Approved DCRX's decision to use marketers to generate referrals;

2. Knew that TRICARE was the source of a majority of DCRX's revenue;

3. Received monthly financial statements, which reported the monthly compounding revenue and commissions paid to marketers; and

4. Funded $2 million in commissions to the marketers.[19]

The district court dismissed the FCA claims on other grounds and never addressed RLH's knowledge of the fraud. The DOJ filed an amended complaint that the defendants, including RLH, promptly moved to dismiss. The private equity firm settled with the government before the court ruled on the second motion to dismiss.

It will hardly be surprising if this case emboldens government prosecutors and whistleblower attorneys to name private equity firms in future FCA suits. Although the initial FCA claims were dismissed on other grounds, the government's view of what facts establish sufficient knowledge for liability to lie with the private equity firm was endorsed by the magistrate's report and recommendation. That said, it is notable to see the extent of the private equity firm's involvement and, according to the government, direction of the alleged fraud scheme. The government alleged that rather than being a mere passive financial investor, RLH actively directed the focus towards compounding and away from the pharmacy's historical business line; was advised that the pharmacy's marketing practices violated the AKS; knew about the allegedly illegal payments to marketers; and even financed these allegedly illegal payments for a period of time.

United States ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.

A second case, currently in active litigation, demonstrates how a private equity firm can be embroiled in high-stakes litigation due to the actions of its portfolio company when there are few allegations of direct participation in the fraudulent conduct. In *United States ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.*, a relator is accusing a mental health provider, South Bay Mental Health Center (South Bay), of providing services by unlicensed, unqualified and unsupervised employees, rendering the claims for the services not payable.[20] The relator has further alleged that the private equity owner of South Bay, H.I.G. Capital, LLC (H.I.G.), which owned South Bay through Community Intervention Services (CIS), caused the false claims because it failed to prevent South Bay from submitting the allegedly fraudulent claims.[21]

The United States declined to intervene in the case and the relator pursued the federal FCA claims on her own.[22] H.I.G. moved to dismiss the federal claims against it, arguing that the relator failed to show that H.I.G. caused the submission of false claims. The district court rejected H.I.G.'s argument that the FCA requires some "affirmative steps to cause the submission of false claims." The court instead reasoned that a defendant may be liable for causing false claims "where the submission of false claims by another entity was the foreseeable result of a business practice" and "a defendant may be liable if it operates under a policy that causes others to present false claims."[23] The court noted that the board of directors of both South Bay and CIS, which included three principals and members of H.I.G., was informed that South Bay was using unlicensed and unqualified providers in violation of state Medicaid requirements, but took no action to correct the problem.[24] The court denied the motion to dismiss because H.I.G. members and principals were alleged to hold a majority of the board of directors, and were directly involved in the operations of South Bay.[25]

Motions for summary judgment in this case were briefed earlier this year. While the case is still pending, investors and observers alike would be well-served by closely following the case to determine how relators can be successful in imposing liability on private equity investors.

United States ex rel. Cho and Baker v. Surgery Partners, Inc. et al

Another case recently dismissed by the district court demonstrates how relators have learned to adjust pleadings to focus on private equity owners of healthcare providers. In *United States ex rel. Cho and Baker v. Surgery Partners, Inc. et al.*,[26] the relators filed their initial *qui tam* complaint on April 25, 2017. The relators named H.I.G. (the same entity named as a defendant in the *South Bay*

case described above) and other private equity firms that had invested in a nationwide pain physician practice group, Surgery Partners, that included numerous pain practices and a urine drug testing laboratory.

The relators alleged that Surgery Partners ordered medically unnecessary sophisticated drug tests and had financial relationships with doctors that violated the Stark Law and AKS. Although alleging ownership of Surgery Partners and the laboratory by the private equity defendants, the initial complaint is devoid of any allegations of management, direction or control by the private equity defendants. The United States settled the case (along with another overlapping case filed in Pennsylvania) with the laboratory, the physician practice group and two individuals in charge of the practice group for $41 million in April 2020.[27] The United States did not settle claims against the private equity owners of the practice, and the relators pursued those claims on their own.

Shortly after the settlement, the relators filed an amended complaint focused on pleading the liability of two private equity investors, H.I.G. and the entity it set up for the investment. Informed by the developments in *RLH* and *South Bay*, the relators added multiple paragraphs seeking to establish management, direction and control of the healthcare provider by the private equity investors. Specifically, the relators added allegations that:

1. Under H.I.G.'s control, leadership, experience and direction, the provider established urine toxicology as a profit center;

2. Partners in H.I.G. became members of the provider's board of directors;

3. H.I.G. was engaged in planning, budgeting and financing the provider;

4. H.I.G. knew that the provider's new business would be fueled by government reimbursement from Medicare-aged patients.

The relators also alleged that Surgery Partners' allegedly illegal activities were done "under the management, control and direction of the H.I.G. Defendants." In fact, the assertion that H.I.G. controlled, supervised, managed or directed Surgery Partners' activities appears in 19 paragraphs in the amended complaint. The similarities among these allegations and those in the previous two cases are clear and point toward the kinds of facts that will be pled in future complaints against private equity firms.

On August 26, 2020, the district court dismissed the relators' complaint on first-to-file grounds under the FCA.[28] Because the suit was dismissed on procedural grounds, the court did not reach the adequacy of the relators' allegations to plead FCA violations by the private equity owner.[29]

The allegations in the three cases represent a continuum of managerial involvement by private equity firms in their operating companies. In *RLH,* the government pled that the private equity firm and its agents were involved in not only the management of the company, but the alleged fraudulent scheme itself. The United States intervened and obtained a settlement in that case. In *South Bay,* the relators pled that the private equity investor was involved in operations, its principals were on the board of directors of the operating company, and they were informed of the conduct that violated Medicaid regulations. Although the government declined intervention on the federal claims, the private equity firm's failure to take action to prevent that non-compliant conduct was sufficient for the relator to survive a motion to dismiss, resulting in years of litigation continuing to this day. Finally, *Surgery Partners*, when initially filed in 2017, appeared to represent the final step of naming the private equity firm based on its ownership of the entity engaged in the alleged fraudulent conduct. The unstated assumption appears to be that the private equity investors must have been aware of the alleged fraudulent conduct and benefited from the conduct. With the lessons of *RLH* and *South Bay*, the relators significantly bolstered their allegations against the private equity firm in their second amended complaint when the private equity firms were the only remaining defendants. Developments in the case law are providing the government and relators a clearer roadmap for establishing private equity investor liability under the FCA for the alleged misdeeds of the operating healthcare providers.

Lessons to Mitigate Risk

Given the stakes, private equity investors would benefit from acting cautiously and being aware of potential minefields. Below are several recommendations and thoughts based on the burgeoning area of the law.

The first lesson from the cases described above is an ominous one. Published court decisions are providing roadmaps to plead future cases against private equity investors when their portfolio companies have engaged in possible healthcare fraud. The *RLH* decision, though novel in obtaining a settlement from the private equity firm, was not terribly surprising. The United States clearly believed RLH and its principals were directly involved in orchestrating the actual alleged fraud. *South Bay*, however, provides future whistleblowers a model to plead sufficient facts to withstand a motion to dismiss, because at least one federal court has found that allegations that

members of the private equity firm were in a position to know about the alleged fraud and yet do nothing about it is a sufficient basis for FCA liability. Finally, the revised allegations in *Surgery Partners* show that relators and their counsel are learning lessons from previous cases regarding pleading allegations against private equity firms.

The key lesson for private equity firms, however, is that now that the genie is out of the bottle, it is urgent to take steps to ensure regulatory compliance of their portfolio companies. These steps concerning compliance include the basic — adopting a compliance program for the healthcare provider that matches the DOJ's guidelines — to the more advanced — creating institutional guardrails to prevent fraud and shield the investors from actual knowledge of any wrongdoing. Such guardrails should include: (1) at the start of any deal a vigorous regulatory due diligence process; (2) ensuring private equity personnel avoid direct involvement in day-to-day operations of the operating company; (3) policies within the private equity company to follow-up on compliance concerns that are brought to its attention; and (4) documentation of investigation and remediation of problems brought to the attention of private equity investor. Destruction in the value of the operating company due to fraud and abuse is bad enough. But the crushing liability associated with the FCA being leveled directly on the assets of the private equity firm, its partners, principals or members is a new level of risk.

There can be little doubt that the degree of management and control the private equity firm exerts over the operating company is the key driver in establishing the level of knowledge of the fraud required to hold the private equity firm liable. A true passive investment relationship where there is little indication that the private equity firm or its agents is engaged in the management of the operating healthcare provider or informed in detail about its operations stands little chance of establishing the knowledge of false claims necessary for liability.

The problem is that the private equity firm is rarely a passive investor. Private equity investments are often predicated on bringing management experience and efficiencies that will increase the value of the operating company, allowing the private equity firm to flip the investment in short order for a favorable return on investment. *South Bay* seems to dictate that the level of knowledge necessary for such involvement may expose the private equity firm to liability for misdeeds in the operating company. Establishing effective compliance programs and institutional guardrails, as described above, may allow for the involvement necessary to maximize returns while mitigating the risk of FCA liability.

Conclusion

As private equity firms continue to invest heavily in the lucrative health industry, attention to compliance in their portfolio companies is increasingly important. Key basic compliance measures are vital. These measures include ensuring that the operating companies have compliance programs in place, establishing procedures to bring compliance concerns to the attention of the private equity firm, and conducting independent audits of portfolio companies. These items are no longer aspirational. More than ever, these basic compliance measures are the bare minimum floor, rather than the ceiling, to ensure sound investments.

1 *Global Healthcare Private Equity and Corporate M&A Report 2020,* Bain & Company, Page. 5.

2 31 U.S.C. §§ 3729-3733.

3 42 U.S.C. § 1320a-7b.

4 42 U.S.C. § 1395nn.

5 21 U.S.C. §§ 301-392.

6 Department of Justice Civil Division, Fraud Statistics Overview, *available at* https://www.justice.gov/opa/press-release/file/1233201/download (last visited Sept. 29, 2020).

7 Penalties are adjusted periodically for inflation. Amounts reflect penalties at time of publication.

8 *See, e.g.* "Department of Justice Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay $2.3 Billion for Fraudulent Marketing," Department of Justice Press Release, Sept. 2, 2009; "Johnson & Johnson to Pay More than $2.2 Billion to Resolve Criminal and Civil Investigations: Allegations Include Off-Label Marketing and Kickbacks to Doctors and Pharmacists," Department of Justice Press Release, Nov. 4, 2013; and "Abbot Labs to Pay $1.5 Billion to Resolve Criminal and Civil Investigations of Off-Label Promotion of Depakote," Department of Justice Press Release, May 7, 2012.

9 Department of Justice Civil Division, Fraud Statistics Overview, *available at* https://www.justice.gov/opa/press-release/file/1233201/download (last visited Sept. 29, 2020).

10 31 U.S.C. § 3730(d).

11 *Id.*

12 "United States Resolves $237 Million False Claims Act Judgment Against South Carolina Hospital that Made Illegal Payments to Referring Physicians," DOJ Press Release, Oct. 16, 2015.

13 "Department of Justice Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay $2.3 Billion for Fraudulent Marketing," Department of Justice Press Release, Sept. 2, 2009.

14 West Virginia Hospital Agrees to Pay $50 Million to Settle Allegations Concerning Improper Compensation To Referring Physicians," DOJ Press Release, Sept. 9, 2020.

15 *See* "Individual Accountability in Corporate Wrongdoing," Memorandum of Deputy Attorney General Sally Yates, Sept. 9, 2015.

16 Remarks of Acting Associate Attorney General Bill Baer, American Bar Association 11th National Institute on Civil False Claims Act and Qui Tam Enforcement, June 9, 2016.

17 "Compounding Pharmacy, Two of its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations," DOJ Press Release, Sept. 18, 2019; *United States ex rel. Medrano Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America, et al.,* No. 15-cv-62617 (S.D. Fla.).

18 *United States ex rel. Medrano Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America, et al.,* 2018 WL 6978633, *11.

19 *Id.*

20 *United States and the Commonwealth of Massachusetts ex rel. Christine Martino-Fleming v. South Bay Mental Health Center, Inc., et al.*, 2018 WL 4539684, at *2 (D.Mass, 2018).

21 *Id. at* *3.

22 The Commonwealth of Massachusetts intervened and filed a separate Complaint in Intervention on state law claims. *United States and the Commonwealth of Massachusetts ex rel. Christine Martino-Fleming v. South Bay Mental Health Center, Inc., et al,* Case. No. 15-cv-13065 (Docket No. 84, Complaint in Intervention of the Commonwealth of Massachusetts).

23 *United States and the Commonwealth of Massachusetts ex rel. Christine Martino-Fleming*, 2018 WL 4539684, at *4-*5.

24 *Id.*

25 *Id.*

26 17-cv-983 (Md. Dist. Fla, Complaint filed Apr. 25, 2017).

27 "Reference Laboratory, Pain Clinic, and Two Individuals Agree to Pay $41 Million to Resolve Allegation of Unnecessary Urine Drug Testing," DOJ Press Release, Apr. 15, 2020.

28 The FCA states in part, "[w]hen a person brings an action... no person other than the Government may intervene or bring a related action based on the fact underlying the pending action." 31 U.S.C. § 3730(b)(5). The district court found that the relators' claims in this suit were barred because of the previously filed (and settled) suit in Pennsylvania. *United States of America, ex rel. Cho and Baker v. H.I.G. Capital, LLC and H.I.G. Surgery Centers, LLC*, 2020 WL 5076712 (M.D. Florida, Aug. 26, 2020).

29 *Id.*

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