No. 24-_____

In the Supreme Court of the United States

ASIF SAYEED, ET AL.,

Petitioners,

v.

STOP ILLINOIS HEALTH CARE FRAUD LLC,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Already pending before the Court is a Petition for a Writ of Certiorari docketed in *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145 (2d Cir. 2024), pet. for cert. docketed, June 7, 2024, that asks: To act "willfully" within the meaning of the Federal Anti-Kickback Statute, must a defendant know that its conduct violates the law? The instant case raises the same question.

2. In addition, the instant case provides an opportunity for the Court to assess the validity and scope of the Seventh Circuit's broad construction of the Anti-Kickback Statute with respect to the concept of "indirect" referrals, which it characterized as "file access." A related question therefore is whether the discovery of qualified seniors who happened to be in a data base provided to Petitioners constituted a "referral" under the Anti-Kickback and False Claims Acts even though they were not referred any particular person.

PARTIES TO THE PROCEEDINGS

Petitioners and Defendants-Appellants below

- Asif Sayeed ("Sayeed")
- Management Principles, Inc. ("MPI"),
- Vital Home & Health Care, Inc. ("Vital")
- Physician Care Services, S.C. ("PCS")

Respondent and Plaintiff-Appellee below

- Stop Illinois Health Care Fraud, LLC

Additional Appearance below

- United States filed an appearance subsequent to the finding of liability against the Petitioners

RULE 29.6 STATEMENT

No publicly held company owns 10% or more of the stock of any of the corporate petitioners (MPI, Vital, and PCS) or any of their respective parent companies.

LIST OF PROCEEDINGS

U.S. Court of Appeals, Seventh Circuit

Nos. 22-3295 and 23-1943

Published at 100 F.4th 899 (7th Cir. 2024) (*Sayeed II*)

Stop Illinois Health Care Fraud, LLC, *Plaintiff-Appellee*, v. Asif Sayeed, Et Al., *Defendants-Appellants*

Judgment: May 2, 2024

Rehearing denied: May 30, 2024

U.S. District Court, N.D. Illinois

No. 12-CV-09306

Stop Illinois Health Care Fraud, LLC, *Plaintiff,* v. Asif Sayeed Et Al., *Defendants*

Judgment: November 30, 2022

U.S. Court of Appeals, Seventh Circuit

No. 19-2635

Published at 957 F.3d 743 (7th Cir. 2020) (*Sayeed I*)

Stop Illinois Health Care Fraud, LLC, *Plaintiff-Appellant*, v. Asif Sayeed, Et Al., *Defendants-Appellees*

Remand Order: June 22, 2020

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OPINIONS BELOW

The Seventh Circuit affirmed the District Court's order finding that Petitioners violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), the Federal False Claims Act, 31 U.S.C. § 3729(a)(1), and the Illinois False Claims Act, 740 ILCS 175/1, et seq. The Seventh Circuit opinion is appended to this petition at App.1a and is reported in the Federal Reporter at 100 F.4th 899 (7th Cir.2024). The denial of the Petition for Rehearing is attached at App.54a and can be found at 2024 U.S. App. LEXIS 13034.

JURISDICTION

The judgment of the Court of Appeals was entered on May 2, 2024. (App.1a) The Seventh Circuit denied Defendants' Petition for Rehearing on May 30, 2024. (App.62a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The following statutory provisions are included in the Appendix:

31 U.S.C. § 3729(a)(1) (App.64a)

42 U.S. Code § 1320a–7b(2)(a) (App.65a)

STATEMENT OF THE CASE

A. Factual Summary

Management Principles Inc. ("MPI") is a 19-year-old company that provided health care management services to Vital Home and Healthcare, Inc. ("Vital"). (R. 227 at 27-28; R. 382 at 9-10). Vital is a 27-year-old home health company that provides home health nursing, including therapy and infusion services, to seniors, mostly to Medicare beneficiaries but also to some commercial patients. (R. 227 at 29). Asif Sayeed ("Sayeed") owns both companies. (*Id*. at 27-28).

Sayeed did not own Physician Care Services, S.C. ("PCS). No longer in business, PCS, like Vital, provided services primarily to Medicare recipients and worked as adjunct providers to patients' primary care physicians. (R. 227 at 29; R. 382 at 10).

Healthcare Consortium of Illinois ("HCI") acted as an intermediary between seniors and the Illinois Department of Aging, one among many intermediaries in Illinois. (R. 227 at 23; R. 382 at 11-12). The Department referred seniors to HCI and other intermediaries based on their specific geographical areas and zip codes, and their care workers' duties included visiting seniors' homes, evaluating seniors' living conditions, and providing what help they needed with such fundamentals as utilities, food, and home maker services. HCI strived to keep seniors independent in their own homes as opposed to nursing homes or in assisted living in order to save the state money by avoiding hospitalization and overutilization of medical resources. (R. 227 at 120-21). The federal government pays certain rates to the

extent seniors can remain in their homes. (*Id*., at 121). Basically, HCI administered from a social perspective, assigning its clients to companies and individuals capable of providing social necessities. When done, HCI generated a bill, and the matter became inactive. (R. 382 at 12).

HCI catered to non-medical needs, but its case workers completed a lengthy questionnaire that captured their clients' health issues, including diagnoses and prescriptions. Occasionally the case worker came across a senior who potentially needed health care related services outside the realm of what HCI coordinated. (*Id*. at 11-12). HCI therefore maintained a list of consortium member healthcare companies, that included Vital and PCS, and if needed its care workers would rotate through that list to evenly recommend eligible seniors to one of the member companies. (*Id*. at 24, 31).

Sayeed became familiar with HCI based on interactions with Salim Al Nurridin, HCI's director at the time. Both Sayeed and Al Nurridin had histories of charitable and community involvement. (R. 227 at 29-30, 114-15). In or about the 1990 Christmas season, Sayeed met Al Nurridin while Sayeed was providing winter coats and shoes to children through the Department of Children and Family Services, and Al Nurridin asked him to consider including children Al Nurridin was helping. (*Id*. at 30,). In about 2006 or 2007, Vital began doing business with HCI, and since that time Vital, and later PCS, have been referral sources on HCI's rotation list of home health and medical companies. (*Id*. at 31).

On November 30, 2009, HCI sent out an "alert" to Vital and other community care organizations that

the Department of Aging was cutting its funding. (R. 227 at 33, 36). HCI asked its recipients to write or call the Governor's Office to oppose these cuts in services that had enabled frail, older adults to remain in the community. (*Id*. at 38-39). Nalini Thakrar ("Thakrar," or "Dr. T"[1]), a physician who was no longer practicing but worked for MPI, received the alert on behalf of Vital, and forwarded it to Sayeed for suggestions. (*Id*. at 37).

Sayeed did not think appealing to the Governor's Office would be effective. (*Id*. at 39). He believed the biggest problems in senior healthcare stemmed from a lack of coordinated services. (*Id*., at 33-34, 37-38). He began proposing ways MPI might be able to help mitigate the effects of the pending budget cuts. If HCI seniors needed prescription drugs, for example, Sayeed offered to reach out to manufacturers to see if they would be willing to donate. (*Id*. at 40, 119). Because HCI apparently was going to lack funds needed to deploy the staff necessary to meet with all the seniors, he offered to help by taking over some of the activities HCI care coordinators presently performed, proposing to become a kind of "one-stop shop" to decrease over-utilization. (*Id*. at 41, 120).

To that end MPI prepared a PowerPoint presentation proposing ways MPI might possibly be able to assist HCI in coordinating patient care. The Power Point went beyond services handled by MPI affiliated businesses, as it included helping HCI with such matters

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[1] Dr. Thakrar was referred to as "Dr. T' because some people had difficulty pronouncing her name. (R. 228 at 153. Although a witness initially referred to Dr. T as a nurse, R. 228 at 154, she was a doctor. (R. 228 at 182; R. 227 at 118).

as prescription medicine and durable medical equipment. (*Id* at 45-48; 59). MPI also offered to help HCI by making phone calls to confirm that services were being provided and by creating tracking and intake spreadsheets that HCI could access daily. (*Id*. at 49-51). MPI suggested these client referral spreadsheets would assist HCI care coordinators identify high risk patients and in turn improve the quality of their home visits. (R. 228 at 27).

At the same time Sayeed sensed changes brewing in the industry based on the Affordable Care Act, through which the government was nudging health care risks toward the private sector. (R. 227 at 40). MPI and HCI came up with the idea of a management services agreement ("MSA") to address the funding cuts to help HCI get through this period, but MPI also wanted HCI "to show us – teach us what they do." (*Id*. at 42). Specifically, Sayeed wished to evaluate whether to undertake a more ambitious project, by using his many years of health management experience to form an accountable care organization, an "ACO." (R. 227 at 27, 40-42). [2]

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[2] *See, e.g.*, www.healthcatalyst.com/what-is-an-ACO-definitive-guide-accountable-care-organizations (April 17, 2014):

> The ACO concept is one that is still evolving, but it can be generically defined as a group of health care providers, potentially including doctors, hospitals, health plans and other health care constituents, who voluntarily come together to provide coordinated high-quality care to populations of patients. The goal of coordinated care provided by an ACO is to ensure that patients and populations — especially the chronically ill — get the right care, at the right time and without harm, while avoiding care that has no proven

An ACO required a minimum of 5000 patients and, unlike HMOs, where a physician could operate at multiple facilities, Sayeed understood that a physician could affiliate only with one ACO.[3] (*Id.* at 123). Sayeed

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benefit or represents an unnecessary duplication of services.

[3] *See, e.g.*, American College of Physicians, *Primary Elements of Medicare Shared Saving Program Final Rule*, that ACO requires a 5000 beneficiary minimum, https://www.acponline.org/system/files/documents/aboutacp/chapters/md/kirschner.pdf. *See also* 42 CFR § 425.110(a)(1). *And see* https://en.wikipedia.org/wiki/Accountable_care_organization#cite_ref-Medicare%20Shared Savings_22 (emphasis added below): Per the CMS Shared Savings Program, final regulations required ACO's to,

- Become accountable for the quality, cost, and overall care of its Medicare fee-for-service beneficiaries
- Enter into an agreement with the Secretary to participate in the program for 3 or more years
- Establish a formal legal structure allowing the organization to receive and distribute payments for shared savings to participating providers of services and suppliers
- Include sufficient primary care ACO professionals for its Medicare fee-for-service beneficiaries
- Accept at least 5,000 beneficiaries
- Provide the Secretary with such information as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries, the implementation of quality and other reporting requirements and the determination of payments for shared savings
- Establish a leadership and management structure that includes clinical and administrative systems
- Define processes to promote evidence-based medicine and patient engagement; report on quality and cost measures; coordinate care, such as using of telehealth and remote patient monitoring

figured he had a better chance of recruiting physicians for such an ACO if he could find patients in a concentrated geographic area, but he had no way of going out in the field and finding those 5000 participants on his own. (*Id*., at 123; R. 382 at 25). The information HCI care coordinators collected, however, would provide a sample population of seniors in a specific area that MPI could review with respect to community social and medical needs. ACO's also required reporting requirements relative to the conditions of the patient population and Sayeed hoped to use that information to determine the cost and investment it would take to become one. (R. 382 at 25-26). While MPI's review was helpful for MPI's evaluation of whether to become an ACO, it also benefitted HCI, because the information when viewed collectively, including Dr. T's review, revealed matters of concern, such as patterns of over-utilization, that would be shared with the quality assurance and management team and assist HCI in obtaining grant money. (*Id*. at 83; R. 338 at 32-33). It also helped with MPI's compliance with its quality thresholds. (R. 227 at 83).

Robert Spadoni, general counsel for HCI, crafted a "management services agreement" ("MSA") that MPI and HCI signed. (R. 382 at 16, 22). One provision called

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- Demonstrate that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans
- Not participate in other Medicare shared savings programs
- Take responsibility for distributing savings to participating entities
- Establish a process for evaluating the health needs of the population it serves

for MPI to engage in quality assurance review, and MPI intended to use it to view the demographics of seniors HCI serviced to determine if there were enough potential patients in the area to support an ACO. (*Id.* at 40, 83).

As part of MPI's quality assurance duties under the MSA, the HCI care coordinators' reports contained just the sort of information MPI needed to decide whether it was financially feasible to become an ACO. (R. 226-5 at 7; R. 227 at 51). They revealed such things as how many potential patients suffered from congestive heart failure, chronic obstructive pulmonary disease, or diabetes, and so forth. (*Id.* at 51-52). The MSA was effective December 1st, 2010, and intended to be in effect for 35 months and MPI agreed to pay HCI $5000 a month. (R. 382 at 21-22).

Sayeed estimated he would have had to employ a minimum of 25 employees to get this information some other way, so this $5000 was a reasonable price to pay to evaluate the risk of his investment, which included the investment he would have to make in technology. The payment had no connection to the times HCI care workers recommended seniors to MPI affiliated companies. (*Id.* at 22, 36-38). For that, Vital and PCS continued without interruption receiving referrals pursuant to HCI's preferred providers rotation list. (*Id.* at 22, 39). The execution of the MSA was totally unrelated to the ongoing rotation referrals by the case workers to the providers on their list.

Thus, upon execution of the MSA, Vital and PCS continued to receive referrals through HCI's rotation just as they had since 2007, long before MPI began paying HCI the $5000. (R. 382 at 28, 30). The MSA between HCI and MPI did not alter that relationship,

but now, under the MSA, MPI was able to extract from the documents HCI care coordinators had filled out with social and certain medical information, information on diagnoses, prescription drugs, visits to ER, hospital admissions, physician references, and the like. (R. 382 at 24).

Access to this information, however, did not occur until after HCI care coordinators had visited the seniors' homes and dealt with all the social responsibilities, *i.e.*, arranging for domestic needs like home maker services, food, and electricity, and until after HCI had referred out all the seniors who potentially qualified for medical services, such as doctor visits, home health care, prescriptions, and diagnostic equipment. (R. 227 at 51.) With respect to those seniors in need of home health care specifically, HCI had already consulted the rotation list and recommended the seniors to one of the several home health agencies that provided the appropriate services, including Vital and PCS. Home health agencies and others have already billed and closed the files. (*Id*. at 51; R. 226-5).

As Sayeed explained, when HCI had completed its work and had billed for it, "that's when we get this data." (R. 227 at 107). This informed them, he said, how many seniors in the cohort suffered from which diseases and maladies. (*Id*. at 51-52). The information enabled MPI to obtain a clearer sense of the health needs of the population so it could intelligently assess whether it was financially feasible to form an ACO, both with respect to the patient population and the availability of health care workers to treat them. (*Id*.) MPI looked for patterns to help it forecast or predict future events. (*Id*. at 52).

Occasionally MPI came across someone from this data mining process who had been "passed over," or "missed out," basically someone who apparently needed a physician or home health but had not been recommended. Sayeed testified MPI would put the information on a log that it made available to HCI for its rotation. (R. 382 at 42-43). Sayeed testified that ultimately "[e]very single referral anybody got from HCI it was all through rotation. (*Id*. at 39-40).

Rosetta Cutright Woods ("Woods") testified she had worked for MPI in or around 2012. (R. 228 at 62). Her duties included going to HCI three times a week and reviewing seniors' files, writing down diagnoses and certain contact information. (*Id*. 228 at 63). Back at MPI, Dr. T reviewed the information Woods collected as part of the Quality Assurance chart review and directed Woods to contact certain seniors to see whether services had started and if the senior needed additional services, including services and supplies neither Vital nor PCS were equipped to provide. (*Id*.).

Sayeed testified that if this person qualified for home health care, HCI would be notified and the individual would be returned to the rotational list. MPI was putting that person "on the log and sending it back to HCI, ..." (*Id*. at 42-43). Sayeed testified that MPI's job ended and it reported back to HCI what the client had said. (*Id*. at 43). Ella Grays confirmed it would go back on the list and the Director would decide. (*Id*. at 43). Similar to Ella Grays, discussed *infra*, even though she and Woods worked during different time periods, they indicated if the senior needed a referral for medical services they would go back to the rotation list. (R. 228 at 68).

Prior to that testimony, however, Sayeed answered "yes" to the question of whether Sayeed believed the MSA gave MPI the right to "solicit" HCI's clients for health care services by calling them. (R. 227 at 85-86). The question arose in the context of questioning Sayeed about the Power Point, and Sayeed several times complained that the Plaintiff was alternating between the Power Point and the MSA. Sayeed testified at that time that based on advice of HCI's attorney he thought it was okay if MPI took the information it learned from HCI's data mined files to call the clients who had missed out on needed services and solicit them for health services. (*Id*. at 86.) Sayeed was aware that almost all these clients had already received social and health services and he subsequently clarified, and directly answered the question "[w]as it a part of the purpose of collecting that information to try and solicit these individuals for home health services by your companies?", with a specific "no." (*Id*. at 103) (emphasis added). Plaintiff followed up by asking, "[w]hy not?", and Sayeed responded that "[t]he purpose was to help HCI and to do data mining." (*Id*).

Around the middle of 2012 Sayeed determined he had enough information and decided to abandon the idea of forming an ACO. He felt he did not have enough capital to take the risk. (R. 382 at 28-30). After 18 months he terminated the agreement and ceased paying the $5000, having concluded that becoming an ACO was not financially feasible. (R. 227 at 79, 107).

The only other live factual witness was Ella Grays, a former HCI director, who testified first she did not know about the $5000 per month payment. Petitioners refreshed her memory by showing her an email she had in fact received that attached an unexecuted draft

version of the Management Services Agreement that included the payment provision. (R. 228 at 44). Grays understood HCI's lawyer had drafted the agreement and that its CEO signed off. (*Id.* at 44-45). She had no reason to suspect the agreement was in any way illegal. (*Id.* at 51).

Gray explained, however, that referrals from HCI went out through a rotation, so that consortium members shared referrals equally. (*Id.* at 23). Asked if she was aware that as a part of data mining and data collection MPI employees were calling HCI's clients "to offer them health care services," she testified no, they called to see if services had started "and if there were any additional services needed." (*Id.* at 33). If there was no indication, they would ask if the person needed a doctor and, if so, she would tell the HCI director. Any referral, she said, had to be approved. (*Id.*).

Grays testified she learned later that MPI was investigating to become an ACO. (*Id.* at 31). She recalled conversations about ACOs generally, though not specifically with Sayeed. (*Id.* at 51). She also recalled conversations about data mining, including discussions related specifically to MPI and the Management Services Agreement. (*Compare id.* at 31-32 with 45). HCI discussed data mining during executive meetings, and she was sure she spoke about it with Sayeed. (*Id.* at 31-32; 49-50). On at least a couple of instances she recalled MPI personnel talking to her about the data MPI collected from HCI files and about charts and spreadsheets where MPI compiled information on patient accounts and diagnoses. (*Id.* at 32). She considered the data mining information valuable to HCI for grant creation, as it helped expose patterns of how people were treated for illnesses and the kind of

illnesses HCI clientele suffered, from geographic viewpoints. It also aided in locating funding and training sources. (*Id*. at 47-48).

B. Seventh Circuit Opinion

Following a bench trial, the District Court found MPI knowingly and willfully paid HCI the $5000 a month at least in part so they could review HCI client database files. It found further that MPI allegedly used that access to solicit Medicare eligible clients for home health services from their affiliated companies, a concept MPI denied. MPI received this access only after HCI had completed the task of referring any qualified seniors to home health agencies and doctors, and MPI argued they paid HCI only during an 18-month period when they were exploring whether to form an Accountable Care Organization and had no other practical or economical path to determining whether a potential client base existed in their geographic area.[4]

The Seventh Circuit affirmed the District Court. It held Petitioners knew it was against the law to pay for referrals and assumed MPI intended at least in part to mine HCI's client database for solicitation opportunities when it obtained access to those closed files. (App.7a).

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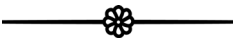
[4] Notably the Plaintiff's theory, that Respondents violated the law by paying HCI $5000 for access to the care coordinator files, was not the theory upon which they brought this case. It alleged originally that MPI paid certain care coordinators with gift cards in order in exchange for referrals, a theory debunked by the witnesses Plaintiff identified to support the allegations during the trial. And *see Sayeed I*, 957 F.3d at 749.

However, because Petitioners were legitimate recipients of HCI client recommendations as part of HCI's routine rotation, the Seventh Circuit ordered a limited remand with respect to damages. It ordered the District Court to determine which claims, if any, on Exhibit 9 were for services provided to patients that HCI referred to Vital or Physician Care through its standard rotation referral system. (App.17a).



REASONS FOR GRANTING THE PETITION

I. INTRODUCTION

In the instant case the Healthcare Consortium of Illinois ("HCI"), a non-governmental organization, contracted with the Department of Aging to help coordinate healthcare for low-income seniors. HCI focused on seniors' social necessities, but in the course of its work HCI would come across seniors with home health and medical needs. HCI maintained a list of member home health organizations and would rotate through that list to refer qualified seniors on an egalitarian basis. Petitioners' companies, Vital and PCS, were on that list.

The questions raised in the instant case have to do with what happened after all the referrals and recommendations had been made and HCI had closed the files. Asif Sayeed and his management company, MPI, which managed Vital and PCS, who are all collectively referred to herein as "Petitioners," entered into a management contract with HCI that included a $5000 monthly payment provision that, among other

things, enabled MPI to obtain access to HCI's files after HCI had closed the files and completed its work.

In *Stop Illinois Health Care Fraud LLC v. Sayeed (Sayeed I)*, 957 F.3d 743 (7th Cir. 2020), the Seventh Circuit reversed a directed verdict in favor of Petitioners by introducing a novel interpretation of what constitutes a "referral" under the Federal Anti-Kickback and False Claims Acts, that while Petitioners did not "directly" pay for the referral of any particular Medicare patient, they may have violated those statutes "indirectly" by virtue of this "file access."[5] Because this "file access" theory originated subsequent to Petitioners' actions in this case, the Seventh Circuit's analysis essentially found Petitioners intended to violate the law pursuant to a theory that did not clearly exist until after the events at issue. The practical effect of the Seventh Circuit's analysis was to find Petitioners liable for having the subjective intent to violate a theory of law that did not clearly exist until after the events at issue in this case.

Petitioners argued the intent of the datamining was not to obtain possible referrals, but to see if there was a potential client base near them geographically, so they could intelligently assess the feasibility of forming an Accountable Care Organization, or "ACO." *See* n. 2 & 3. The instant petition asks the Court to clarify the parameters of the subjective scienter require-

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[5] The Anti-Kickback Statute provides in relevant part that whoever "knowingly and willfully offers or pays any remuneration directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" to refer an individual to a person for the furnishing of services paid for in whole or in part by a Federal health care program. 42 U.S.C § 1320a-7b(b)(2)(A) (emphasis added).

ment in these circumstances, *i.e.*, whether it focuses not on whether a defendant knew generally the law forbade paying for referrals, but whether he acted with the subjective intent to violate that law. It appears to have been answered in opposing ways by different appellate courts and needs to be answered by this Court. *Compare*, *e.g.*, *United States v. Junius*, 739 F.3d 193 (5th Cir. 2013) (willfully under the AKS requires only that defendant willfully committed the act), versus *United States v. Sosa*, 777 F.3d 1279 (11th Cir. 2013) (willfulness requires defendant acted with knowledge its conduct was unlawful).

In addition, the instant case provides an opportunity for the Court to assess the validity and scope of the Seventh Circuit's broad construction of the Anti-Kickback Statute with respect to the concept of "indirect" referrals. During a brief period when Petitioners were exploring whether their geographic area could support the formation of an Accountable Care Organization, Petitioners paid for access to a database of seniors who had previously been vetted for home health needs and found unqualified, ineligible, or otherwise not in need or desirous of such services, or who had already been referred out to various health care agencies. The Seventh Circuit found that Petitioners violated the Anti-Kickback and False Claims Acts simply by paying for "access" to these files to find solicitation opportunities, when in fact there could be no such referrals anticipated since all such referrals had been taken care of before Petitioners ever saw them. This is especially apparent as there was no evidence of calls being made the whole time of the contract.

II. CERTIORARI SHOULD BE GRANTED TO CLARIFY THE INTENT REQUIRED TO VIOLATE THE ANTI-KICKBACK AND FALSE CLAIMS ACTS

HCI, a non-governmental organization, contracted with the Department of Aging to help it care for low-income seniors, mostly by taking care of their seniors' social needs. Occasionally it came across a senior needing home health related services. For that possibility, HCI maintained a list of member home health agencies and its care workers would rotate referrals through the list. Asif Sayeed owned MPI, a management company that managed the part-time personnel of two other companies, Vital and PCS, both of which were among the companies that received referrals pursuant to HCI's rotation.

In late 2010 HCI and MPI entered into a management services agreement that included a provision wherein MPI would pay HCI $5000 a month that, in its terms and responsibilities gave MPI access to HCI client files after HCI had performed is task of caring for the seniors' social needs, made any medical and home health referrals that needed to be made, billed the Department for its work and closed the files. Sayeed testified he sought this information for purposes of quality assurance and because he was exploring whether to form an Accountable Care Organization, an "ACO[6]", and he needed to see if there was enough potential business in a discrete geographic area that

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[6] An ACO might be thought of as an alternative version of an HMO. But according to Sayeed's understanding, unlike HMO's where physicians can work at multiple HMO's, with ACO's the physician can only work at one. R. 227 at 123. Thus, the need for geographically close clientele. *See* n. 2 & 3, *supra*.

would make the formation worthwhile. Sayeed hoped HCI's database would provide that information.

MPI anticipated mining the HCI data for 35 months, but after 18 months Sayeed abandoned the idea of forming an ACO. Accordingly, he stopped making the $5000 payments. As it happened, however, during the 18-month period when MPI was making these payments, it occasionally came across seniors who had been "passed over," *i.e.*, seniors who qualified for health care services but who HCI had not referred out pursuant to HCI's standard rotation.

The District Court initially directed a verdict in favor of Petitioners, finding that the Plaintiff had failed to show any violation of the law. In *Stop Illinois Health Care Fraud LLC v. Sayeed (Sayeed I)*, 957 F.3d 743 (7th Cir. 2020), *see* App.46a, however, the Seventh Circuit reversed the District Court's directed finding against the Plaintiff, but it did so by adopting a novel "file access" kickback theory that had not been applied in any prior kickback cause of action. Specifically, the Seventh Circuit sent the case back to the District Court to explain whether the defendants' "data mining" constituted an indirect (as opposed to direct) referral and arguably violated those Acts.

The Federal Anti-Kickback Statute prohibits the "knowing and willful" payment of remuneration to induce or reward patient referrals. 42 U.S.C. § 1320a-7b(b). The instant case therefore has implications with respect to how and where at the crossroads this novel interpretation meets this Court's recently decided decision in *United States ex rel. Schutte v. SuperValu Inc.*, 143 S.Ct. 1391, 1394 (2023), which focused on a person's "knowledge and subjective beliefs" that he was doing something illegal and not what an objectively

reasonable person would have known and believed. Petitioners submit that the factual question in the instant case should have been whether Petitioners "willfully" violated the AKBS and FCA when they paid for access to a database that should not have, but arguably, possibly, did include seniors who should have been referred for services but for some reason had been overlooked.

It would seem counterintuitive to assume Sayeed, with decades of experience in health care, would pay $5000 for referrals in a database where any potential referrals had already been rotated through to all the Consortium members already. Clearly, he datamined for a different reason, he said it was to assess whether HCI's client population would support an ACO. Moreover, "file access" cannot be a sufficient basis in and of itself to constitute a referral because there can be no "referral" if there was no fraudulent claim submitted, and in the instant case the Plaintiff did not identify a single claim that resulted from the file access. *Grant ex rel. United States v. Zorn*, 107 F.4th 782 (8th Cir. 2024).

The Seventh Circuit's interpretation of the scienter requirement focused on whether Petitioners knew it was improper to pay a kickback for a referral as opposed to whether Petitioner knew or should have known what they were doing constituted a violation of the law. While the statute covers remunerations paid both "directly and indirectly," it does not specifically define an "indirect referral," encompasses payment only to a "person," and requires it have the specific purpose of inducing the recipient to refer potential clients. *See* 42 U.S.C § 1320a-7b(b)(2)(A). All the individuals who qualified for services on the database MPI received had

already been referred out to the various home health agencies, including to the MPI affiliated companies, Vital and PCS.

Along the way the Seventh Circuit rejected Sayeed's "safe harbor" defense, because the agreement did not specifically make any reference to data mining or client solicitation. *See* 42 CFR § 1001.952(d)(ii) (requiring that the agency agreement covers all the services to be provided over the term of the agreement). The management services agreement may not have clearly set out everything required to be covered, as the Seventh Circuit so noted, but it obviously did not conceal the critical fact that MPI was paying HCI every month the sum of $5000. Holding as it did, the Seventh Circuit's construction, if followed by other courts, threatens to entrap persons who, in a highly regulated industry like the instant one, knowing what the law forbids, make a good faith but imperfect effort to meet that law. Sayeed did so though a management services agreement drafted by the lawyer for HCI, who more than anyone could be reasonably relied upon to evaluate whether a proposal was appropriate or not.

The appropriate question under *Schutte* should have been whether Sayeed subjectively <u>believed</u> the management services agreement represented a safe harbor protecting his conduct. A lawyer for HCI drafted the agreement – Sayeed is not a lawyer – and it did provide specifically for "chart review" (MSA, R. 226-3 at 7), which necessarily would encompass reviewing the data HCI care coordinators had gathered as part of their duties for HCI. That "chart review" was one of MPI's duties with respect to oversight and participation in MPI's quality assurance programs. Data

mining was chart review, which was exactly what MPI was doing through data mining.

That the agreement did not specifically state that MPI would be soliciting HCI "missed out" seniors for health care services was because soliciting was not the contemplated intent of the file access. That only came about when the "chart review" unexpectedly revealed a senior who should have been, but unfortunately had not been identified as eligible for services. That was, in effect, an accident in the process, and if Petitioners followed up on those accidents it can hardly be said the intent of the agreement was to mine for referrals.[7]

In the *Schutte* case this Court stated that the FCA's scienter standards are plainly satisfied if a defendant consciously believed his claims were false, *i.e.,* knowing they arose out of an improperly obtained referral. *Schutte*, 143 S.Ct. at 1402. The instant petition asks the Court to expand on whether these standards can be satisfied when a defendant's conscious belief is that his claims are true, *i.e.,* that he did not believe his actions arose out of an improperly obtained referral. The standard for subjective belief should mirror the same standard applied in *Ruan v. United States*, 142 S.Ct. 2370 (2022), albeit a controlled substances case, that a defendant is not criminally liable unless the

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[7] Sayeed had answered "yes" to several questions suggesting that MPI "solicited" clients through the file access (R. 227 at 85-86), but he later clarified that he did not do so to obtain clients for his companies. Sayeed apparently did not construe the word "solicited" in the sense of "soliciting" seniors for his companies (*Id.* at 103), as opposed to determining whether qualified seniors would want to know the availability of services. In his later testimony he claimed that all those "solicited" seniors were returned to the rotation. R. 382 at 39-41).

Government proved "that he knew or intended that his conduct was unauthorized."

The Seventh Circuit noted Sayeed was responsible because he allegedly knew one could not pay kickbacks to obtain a patient, *see* App.7a, but if *Ruan* applies that only gets the Plaintiff halfway there. The Court should grant this petition and hold in these civil cases that a Plaintiff must show Petitioners knew their conduct was unauthorized – as opposed to simply whether they engaged in conduct that in retrospect turns out to be, allegedly, illegal.

Here, the District Court originally granted a directed verdict in favor of the Petitioners, finding that the management services agreement did not indicate any expectation of referrals and crediting Sayeed's denial that referrals were the purpose, noting as well the fact that the HCI attorney signed off on the agreement, indicating there was nothing wrong or illegal about it. (R. 216 at 6). The District Court had therefore found no evidence the agreement was intended to induce referrals. The District Court stated:

> [S]everal witnesses testified that the management services agreement did not indicate any expectations of referrals or other kickbacks from either HCI or MPI. Sayeed testified at trial that referrals were not the purpose of the $5,000 monthly payments made pursuant to the agreement. HCI's attorney Spadoni signed off on the agreement, indicating that there was nothing wrong or illegal about the agreement.

R. 216 at 6.

The District Court's earlier factual findings support the conclusion that Petitioners' subjective beliefs were reasonable and that Petitioners did not intend to violate the law. It was only years later, when the Seventh Circuit reversed the District Court in *Sayeed I*, that the Seventh Circuit found that this same conduct may have represented a "less direct," or, in the words of the statute, an "indirect" theory of a referral, *see Sayeed I*, R. 216 at 11, App.4a, upon which it found Petitioners potentially liable. Yet to the common man, in the most common parlance, the construct of "indirect" payments relates to such things as payment to a middleman as opposed directly to the defendant. *See, e.g., United States v. Krikheli*, 461 Fed. Appx. 7 (2d Cir. 2012) (audio and video recordings demonstrated the Krikhelis paid physicians "through middlemen"). The Seventh Circuit affirmed the judgment here not because they allegedly hid their participation. They openly purchased access to a retired database that for all intents and purposes should not have included any seniors at all who had qualified for a referral but been overlooked.

The need to grant this petition is further exemplified by the fact that this issue will certainly repeat itself. In fact, it will arrive in this Court if the Court grants the recently docketed Petition for Writ of Certiorari in *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 157 (2d Cir. 2024), *petition for cert. docketed*, No. 23-1293 (Case No. 23-1293, June 11, 2024). In *McKesson* the Second Circuit held that to violate such acts a defendant must act with knowledge that his conduct violates the law, exactly what Petitioner argues the Seventh Circuit did not require here. The Seventh Circuit opinion creates a clear

fission in the Circuits and requires this Court's intervention.

The *McKesson* court affirmed the District Court's dismissal of the case because the complaint did not adequately allege that defendants knew their conduct violated the law. Several appellate and lower courts agree with *McKesson* and the resolution the Petitioners seek here, *see McKesson*, 96 F.4th at 154-55 (citing cases), that to establish a knowing and willful violation, Relator's complaint must allege the defendants acted with knowledge their conduct was unlawful. *See also, e.g., Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989); *United States ex rel. Langer v. Zimmer Blonet Holdings, Inc.*, 2024 U.S.Dist. LEXIS 137176 (D. Mass.). *And see United States ex rel. Sheldon v. Forest Labs.*, LLC, 2024 U.S. Dist. LEXIS 129331 (D.Md.), (rejecting the notion that the requisite scienter depends largely on whether defendant was "familiar" with the operative statute and stating that "I do not consider Forest's assumed familiarity with the statutory definition of 'Best Price' a sufficient basis to establish that Forest acted with 'actual knowledge' that its reports were false.").

This Court too should hold that Petitioners had to know that data mining violated the law. *United States v. Clough*, 978 F.3d 810, 821 (1st Cir. 2020). *See also United States ex rel. Graziosi v. R1 RCM, Inc.*, 2020 U.S. Dist. LEXIS 223086 (N.D.Il.), at *50, *citing and quoting United States v. Patel,* 17 F.Supp.3d 814, 824 (N.D.Il. 2014, *aff'd*, 778 F.3d 607 (7th Cir. 2015), and *citing United States ex rel. Suarez v. AbbVie Inc.*, 2019 U.S. Dist. LEXIS 169090 (N.D.Il.), at *13. Using "willfully" in conjunction with "knowingly" means more

than acting intentionally, *United States v. Williams*, 218 F.Supp.3d 730, 736 (N.D.Il. 2016), *citing and quoting United States v. Wheeler*, 540 F.3d 683, 690 (7th Cir. 2008), which in the anti-kickback context means "voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose or disregard of the law." *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013). *See also United States v. Gibson*, 875 F.3d 179, 188 (5th Cir. 2017) (plaintiff must show defendants specifically intended to do something the law forbids). *And see Ruan*, 142 S.Ct. at 2382 (2022) (Government must prove the defendant knowingly and intentionally acted in an unauthorized manner). In *McKesson* the Second Circuit noted that this Court in *Bryan v. United States*, 524 U.S. 184, 191 (1996), said the same thing. *McKesson*, 96 F.4th at 154-55, *citing Bryan*, 524 U.S. at 191-92 ("Government must prove that the defendant acted with knowledge that his conduct was unlawful."). *See also United States v. Kukushkin*, 61 F.3d 327, 332 (2d Cir. 2023).

If Sayeed ended up using some of the datamined information to solicit clients for his companies, a factual finding Sayeed denied but the Seventh Circuit repeated (both courts using testimony from the Power Point idea not implemented), it does not follow that he had the subjective intent to violate the law.[8] One can

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[8] To be clear, Sayeed testified MPI did not solicit any HCI clients through data mining at all. Prior to Sayeed presenting his defense the Plaintiff asked him questions about "soliciting" seniors, but it was unclear he construed "solicited" in the manner Plaintiff meant the word to connote. He later testified qualified seniors were in fact returned to rotation (R. 382 at 39-41), a statement the District Court admittedly did not find credible. *See* App.22a. The Seventh Circuit editorially exaggerates Sayeed's

easily imagine that neither the Department of Aging nor HCI would have wanted him to ignore the needs of qualified seniors he discovered in the course of data mining. Providing health care to seniors was the whole point of the program, Petitioners were on the referral list, HCI had completed its task of taking care of seniors' social needs and referring out those who qualified for needing home health, and to ignore seniors who should have been referred would be antithetical to the program.

And, even if Sayeed secretly harbored some hope that the data mining might reveal some "missed out" senior – and he specifically denied that he did by virtue of his clarifying testimony that the process was to return such qualified seniors to the routine rotation-there are many lower court decisions holding that "[a] hope, expectation, or belief that referrals may ensue from remuneration for legitimate services is not a violation of the Anti-Kickback Statute." *United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000) (emphasis added); *United States v. Rogan*, 459 F.Supp.2d 692, 714 (N.D.Il. 2006). In the instant case, given the fact that qualified seniors had already been referred Sayeed could not have had any hope or expectation of obtaining referrals, still more reason why referrals was not the intent of the management services agreement payment or the mining. As noted above, a person with his knowledge in the health care business would not likely pay for such a hope.

The *McClatchey* court distinguished between a "motivating factor" and a "collateral hope or expect-

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testimony, however, when suggesting he ever said it was "his intent to mine for . . . for solicitation opportunities." *See* App.7a.

ation." *Id.*, 217 F.3d at 834, n.7. It has been cited in numerous non-precedential and district court cases, which shows it has an impact on the state of the law. *See, e.g., United States v. Omnicare, Inc.*, 663 Fed.Appx. 368, 374 (5th Cir. 2016); *United States ex rel. Arnstein v. Teva Pharms USA, Inc.*, 560 F.Supp.3d 412, 420 (D.C. Mass. 2021), and *United States v. Holland*, 396 F.Supp.3d 1210, 1239 (N.D. Ga. 2019), *district court and non-precedential opinions all citing McClatchey*, 217 F.3d at 834 (in holding that there is no AKS violation where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes). "The former subjects the payor-company to liability under the AKS, while the latter does not." *United States v. Regeneron Pharms., Inc.*, 2020 U.S. Dist. LEXIS 227643 (D. Mass.) (also *citing McClatchey*). *See also, e.g., United States v. Omnicare, Inc.*, 663 Fed. Appx. 368, 375 (5th Cir. 2016) ("Although Omnicare may have hoped for Medicare and Medicaid referrals, absent any evidence that Omnicare designed its settlement negotiations and debt collection practices to induce such referrals, Relator cannot show an AKS violation.").

HCI's own lawyer helped draft the management services agreement, would obviously have known of the $5000 payment and Sayeed's unrebutted testimony was that the lawyer knew what Petitioners intended to do. The witness Ella Grays testified HCI's lawyer looked over and approved the contract with its $5000 payment, as well. R. 228 at 43-44. MPI paid only during the period when it was considering whether to form an ACO, and Sayeed testified about the enormous costs if he tried to obtain this information some other way. Indeed, it is illogical to assume that a person like Sayeed, with all his years in the industry, would be

paying $5000 a month for the purpose of reviewing a database that was not expected to reveal any seniors who qualified for home health care who had not been outsourced already.

With respect to his intent, there was no basis to dispute Sayeed's understanding that the agreement allowed data mining, or that his understanding was not honestly held. *See, e.g., United States ex rel. Behnke v. CVS Caremark Corp*., 2024 U.S. Dist. LEXIS 60163 (E.D.Pa.), at *133-34 ("Thus, if Caremark were innocently unaware that CMS's regulations required it to report the guaranteed average price as to the actual price of drugs, Caremark would lack scienter. On the other hand, if Caremark knew, deliberately ignored, or recklessly disregarded that average price reporting was required, scienter would be met."). The Seventh Circuit's construction of scienter seems to assume that if a defendant knew payments were against the law he knowingly violated the law, when Petitioner believes the court needs to make clear it requires more than that, the more being that the defendant intended to do something he or she knew amounted to an actual violation of that law. If anything, the Seventh Circuit's construction of intent approaches a version of strict liability.

As noted *supra*, this Court in *Schutte* said: "FCA's scienter standards are plainly satisfied by a defendant's conscious belief that his claims are false." *Schutte*, 143 S.Ct. at 1402. *See also United States ex rel. Miller v. Reckitt Bencklisher Grp. PLC*, 2023 U.S. Dist. LEXIS 186884 (W.D.Va.), ¶ 45 (quoting *Schutte*). The instant petition asks the Court to expand on that. To what extent can the FCA standards be satisfied when the

defendant's conscious belief is that his claims are true?

Several lower courts have taken the position that the *Ruan* standard in context applies only to the *mens rea* in criminal cases. *See, e.g., United States ex rel. Shiloh v. Phila. Vascular Inst., LLC*, 2024 U.S. Dist. LEXIS 59133, at n. 13, *and citing United States v. Spivack*, 2022 U.S. Dist. LEXIS 162608 (E.D. Pa.). *See also United States ex rel. Suarez v. AbbVie, Inc.*, 503 F.Supp.3d 711, 735 (N.D.Il. 2020), *citing Suarez I*, 2019 U.S. Dist. LEXIS 169090, at *13 ("Relator's burden is to allege facts supporting an inference that AbbVie thought the Ambassador Program was impermissible."). But the Anti-Kickback Statute is essentially a criminal statute, however, and the *mens rea* should be the same. *McKesson*, 96 F.4th at 154-55, *citing Pfizer, Inc. v. U.S. Department of Health & Human Services*, 42 F.4th 67, 77 (2d Cir. 2002). ("Although *Pfizer* addressed a slightly different issue than what we now face, its discussion of the term "willfully" in the AKS is evidence that we have understood that term as it is typically interpreted in federal criminal law. Moreover, the interpretation suggested in *Pfizer* aligns with the approach to the AKS taken by several of our sister circuits, which have held or implied that to be liable under the AKS, defendants must know that their particular conduct was wrongful."), *citing cases*.

The Court should grant this Petition for a Writ of Certiorari and address whether the question of the element of acting "willingly" in the Anti-Kickback Act requires an intent to actually violate the law, as opposed to doing the acts that might later be construed as such a violation.

III. CERTIORARI SHOULD BE GRANTED TO CLARIFY THE PARAMETERS OF THE SEVENTH CIRCUIT'S "FILE ACCESS" THEORY AND WHETHER IT CAN APPLY AT ALL

Petitioners submit this certiorari petition should be granted for the Court to assess the viability and parameters of the Seventh Circuit's unique "file access" theory of liability under the Federal Anti-Kickback Statute and by extension the Federal False Claims Act. As noted above, pursuant to the management services agreement Petitioners paid $5000 a month for an 18-month period during which time they were assessing the viability of forming an ACO. Pursuant to that agreement they were given access to the case assessment reports that HCI care workers created pursuant to the performance of their duties in the aid of the Department of Aging.

This case also presents questions with respect to what constitutes a an illegal "referral." The Seventh Circuit has interpreted the concept of a "referral" so that giving MPI its clients' names and contact information was just as much a "referral" under the kickback laws as directing MPI to a client in particular. Petitioners submit that such a theory absent the subjective intent to actually violate the law threatens to criminalize common practices not much different from the rotation process the HCI actively employed when, acting as a virtual agent of the Government, collected a fee from health care organizations to become "members" of the consortium and be eligible for "access" to a referral.

No one testified that Petitioners received this information for the purpose of acquiring referrals. The only testimony was that MPI received this informa-

tion for an 18-month period to aid in their assessment whether to form an Accountable Care Organization which allowed it to perform quality assurance under the management services agreement. Coming across a senior who qualified for but had "missed out" Medicare funded home health care the District Court found that Petitioners solicited those seniors for services.[9]

For the same reasons discussed in the previous section, these alleged solicitations did not constitute improper referrals. HCI did not refer any particular senior to Petitioners. The access it provided came after HCI had already referred qualified seniors pursuant to the standard rotation process. Thus, the payment for this "file access" did not have to do with obtaining referrals, and Petitioners abandoned the idea of becoming an ACO they stopped making the payments, showing that the $5000 payment had to do with the ACO investigation and not to solicit clients. Affirming this underdeveloped "file access" theory would criminalize the entire process, because all the Consortium members in some manner paid for referrals just by becoming Consortium members. The law should not be so dangerously unclear.

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[9] Sayeed denied that they solicited seniors for MPI related companies. He explained that when MPI discovered a "missed out" senior who qualified for home health care MPI would alert HCI so the senior could be returned to the routine referral rotation. (R. 382 at 39-41).

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that this Petition for Writ of Certiorari be granted.

Respectfully submitted,

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