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THE DIFFERENCES AND SIMILARITIES BETWEEN AMERICAN AND ITALIAN HEALTHCARE FRAUD, WASTE, AND ABUSE LAWS: PART 1

by Pamela Coyle Brecht, Paola Sangiovanni, and Marc Stephen Raspanti

Pamela Coyle Brecht, Esq., Avv.

Paola Sangiovanni

Marc Stephen Raspanti, Esq.

Pamela Coyle Brecht *(pcb@pietragallo.com) serves as Pietragallo Gordon Alfano Bosick & Raspanti LLP's Practice Chair for the firm's global Qui Tam/False Claims Act Practice Group in Philadelphia, PA.* ***Paola Sangiovanni*** *(paola.sangiovanni@grplex.com) is a life sciences lawyer and partner in the law firm of Gitti and Partners, which is located in Milan, Italy. Her clients include med tech, pharma, and healthcare providers.* ***Marc Stephen Raspanti*** *(msr@pietragallo.com) is a name partner of Pietragallo Gordon Alfano Bosick & Raspanti LLP, located in Philadelphia, Pennsylvania. He is the founder of the firm's White Collar Criminal Defense Practice Group as well as the firm's Qui Tam/False Claims Act Practice Group.*

This is Part 1 of a three-part series discussing the similarities and differences between the US and Italian healthcare fraud, waste, and abuse laws. Part 2 of this series will be published in the December issue of Compliance Today, *and Part 3 will be published in January 2022 issue of the magazine.*

The United States of America and the Italian Republic share many common ideals. America was named after Amerigo Vespucci, an Italian explorer.[1] The American Constitution is based on the principle of government "of the people, by the people, for the people." The Italian Constitution embodies this same principle in the ideals of sovereignty to the people: "La sovranità appartiene al popolo." As of 2003, almost 16 million Americans claimed to have had Italian heritage.[2] With shared values, our two countries have forged an indelible alliance. These allied nations work together as world leaders in responding to a wide variety of economic, political, medical, technological, and scientific challenges that confront a rapidly changing world.

A major challenge confronting both America and Italy is providing a healthcare system that extends medical treatment that is effective, innovative, devoid of fraud, and cost efficient. While the healthcare systems in America and Italy differ in many respects, they suffer from the same obstacles: fraud, waste, and abuse. Both countries take these problems seriously. For example, in America, the federal government recovered more than $2.2 billion in 2020 alone from healthcare fraud and false claims,[3] while in Italy the National Anti-Corruption Authority (Autorità Nazionale Anticorruzione) is actively monitoring, preventing, and responding to corruption, as well as issuing anti-corruption plans.

This article highlights laws enacted in America and Italy to combat fraud, waste, and abuse, showing important similarities as well as differences between these enforcement efforts. Given the close historical and commercial ties between America and Italy, including healthcare companies that regularly operate in both countries, all stakeholders involved in healthcare (i.e., financial stakeholders, manufacturers, marketers, distributors, providers, and attorneys) should have a working understanding of the systems to deter and respond to fraud, waste, and abuse.

Additionally, due to the worldwide COVID-19 pandemic, two simultaneous phenomena have emerged: (1) an unprecedented increase of healthcare spending by governments and (2) a focus on fast performance of urgent public

healthcare services, sometimes at the expense of values such as transparency, controls, and application of corruption prevention measures. This article aims to also understand how anti-fraud policies in America and Italy will be affected by the unprecedented spending in response to the pandemic that crippled both countries for over a year.

The American and Italian healthcare systems

Despite many complicated differences in healthcare spending, both America and Italy commit extraordinary public resources to healthcare delivery. One primary distinction between the two is that the American healthcare delivery system is a hybrid of public and private payers, while Italy relies predominantly on a universal public healthcare system augmented by a growing private system.

The American healthcare system: A public-private hybrid

To label healthcare in America as one "system" is a misnomer. Americans receive medical care through a hybrid of two different but interrelated healthcare delivery systems: (1) the government-funded or "public" health system, which has federal and state components, and (2) the numerous for-profit and nonprofit private health insurers. This hybrid system provided some measure of healthcare coverage to 92% of Americans in 2019.[4]

The first prong of the American hybrid health system is government-funded public insurance. The main pillars of government-funded insurance are the giant Medicare and Medicaid systems (although there are other significant publicly funded health insurance programs such as the Children's Health Insurance Program; TRICARE, which is the health system for the US military; the Veterans Health Administration, which is the health system for US military veterans; and the Federal Employees Health Benefits Program and similar programs throughout the country that cover state employees). Created in 1965, Medicare provides government-funded healthcare to millions of Americans aged 65 and over. Over time, Medicare has expanded to include Part A (hospital insurance); Part B (medical insurance); Part C (Medicare Advantage plans, which are "managed care" plans funded on a per member, per month basis rather than the fee-for-service coverage under Parts A and B); and most recently—as of 2006—the massive and costly Part D (drug coverage).

Additionally, Medicare has expanded to cover individuals over 65, disabled individuals, and those with end-stage renal disease or those requiring a kidney transplant. By 2018, 60 million people had been enrolled in Medicare, and Medicare spending reached more than $704 billion[5] (almost 20% of the total spending on healthcare in America).[6] The Centers for Medicare & Medicaid Services, a division of the United States Department of Health & Human Services, administers this behemoth government-funded healthcare program.

The second major pillar of American government-funded insurance is the Medicaid system. Medicaid, also established in 1965, provides government-funded healthcare for poor and low-income families. Like Medicare, the Medicaid program provides hospital insurance, medical insurance, managed care, and prescription drug coverage. Unlike Medicare, however, the Medicaid program is not funded solely by the federal government. Rather, the Medicaid program is *jointly* funded by the federal government and each of 50 states, five territories of the United States, and District of Columbia. Unlike Medicare, the dual-funded Medicaid program is administered by the states, and programs can vary significantly from state to state. As of April of this year, the Medicaid program covered more than 75 million Americans.[7] Medicaid spending nationwide grew to $613.5 billion in 2019, a 2.9% increase from the previous year.[8]

Anti-fraud policies in America and Italy will be affected by the unprecedented spending in response to the pandemic.

The third pillar of the American hybrid health system is the private health insurance market. In 2019, according to the U.S. Census Bureau, an estimated 68% of Americans had private health insurance.[9] Also in 2019, private insurance spending was $1.195 billion per year.[10] The most

common form of private insurance is employer-based insurance in which nongovernmental employers offer their employees group insurance plans, typically administered by private, for-profit insurance companies. Additionally, in 2019, about 10% of Americans received private insurance not through their employers, but rather by purchasing coverage directly from insurance companies.[11] Private insurance companies are, as the name suggests, run privately and are regulated at the state level by each state's insurance department. These insurance departments guard against fraud, waste, and abuse through their own sophisticated internal fraud monitoring and special investigations units often directed by former law enforcement personnel.

The Italian healthcare system: Primarily a single, government-funded payer

The Italian healthcare system relies fundamentally, but not solely, on public universal healthcare services. The national health service (Servizio Sanitario Nazionale, or SSN) was established more than 40 years ago[12] to ensure health to Italian citizens while respecting human dignity. The basic principles of the SSN are universality, equity, and solidarity. SSN's goals include (i) collective preventive public healthcare, (ii) healthcare assistance in public hospitals, and (iii) healthcare assistance through territorial providers other than hospitals. Responsibility for administering the SSN has gradually shifted from the national level to each of the 20 regions of Italy, which are financially responsible for managing public healthcare delivery and costs. This additional responsibility of expense management has rendered the system even more difficult to administer and has exposed regional inequalities in healthcare services, as well as the health migration as patients seek regions with better healthcare services.

The SSN is tasked with developing the standards for healthcare to be provided to all citizens (Livelli Essenziali di Assistenza, or LEA), as determined by national decree,[13] most recently amended in 2017. LEA healthcare services under the SSN are entirely free for citizens with income below established thresholds as well as for those who are affected by certain conditions. All other citizens are required to contribute to the cost of their healthcare services.

In order to obtain healthcare services beyond LEA coverage guaranteed by the SSN, many Italians contribute to private collective funds or have entered into private insurance policies. Therefore, the Italian healthcare system is built on the following three pillars:

1. The SSN, covering the basic universal services (LEA);
2. A system of collective private insurance to fund services beyond LEA; and

3. Private insurance policies covering individuals or families.

Over time, the resources available to cover the first pillar, the SSN, have decreased, particularly as investments have been insufficient to keep up with rising costs. On the other hand, the second and third pillars have become more popular,[14] and therefore, services under LEA have failed to meet citizens' needs.

Currently, the cost of providing healthcare in Italy is still borne predominantly by the national health system as follows:

- 74,2% of healthcare is provided through a single public or regional payer;
- 25,8% of healthcare is funded privately: of that portion, and the great majority of such private funding is made directly out of pocket by the patient.[15]

In addition to the public hospitals, there also are many private hospitals as well as hospital chains. Such private hospitals have entered into national or regional agreements to provide healthcare under SSN and obtain reimbursements from the government.

American healthcare enforcement: A complex regulatory patchwork

In America, the prevention of fraud, waste, and abuse in the hybrid healthcare system is spread across a complex patchwork of actors: federal and state law enforcement agencies and investigators; private insurance company fraud investigations/monitoring departments; and private-citizen whistleblowers. In addition, numerous federal and state criminal and civil laws and regulations apply to the healthcare system. Untangling this web is essential to understanding the American healthcare system and avoiding entanglement in a healthcare fraud investigation and/or civil or criminal prosecution.

America's healthcare fraud enforcement 'team'

Although the various groups responsible for healthcare enforcement in America often cooperate, calling them a unified team oversimplifies these groups. However, the government agencies, private organizations—and individuals—play a key role in reducing fraud in the multitrillion-dollar American healthcare system. Any practitioner involved in healthcare should understand the role played by each member of America's highly diversified healthcare fraud prevention team.

Government (federal and state) law enforcement agencies and investigators primarily police the American healthcare system. At the federal level, several agencies share these duties, including the U.S. Department of Health & Human Services' Office of Inspector General, largely charged with investigating allegations of fraud against the Medicare and Medicaid programs; the United States Department of Justice and its 93 separate United States attorneys, who initiate and prosecute criminal and civil healthcare fraud cases on behalf of the federal government; and the United States Food and Drug Administration's Office of Criminal Investigations, which investigates alleged illegal practices by pharmaceutical and medical device manufacturers. At the state level, prosecution of potential healthcare fraud is shared among 56 individual attorneys general; 53 individual state Medicaid Fraud Control Units, who work together through the National Association of Medicaid Fraud Control Units, which promotes efficiency in healthcare fraud prosecutions by sharing information and dividing responsibility for investigating and prosecuting fraud cases on behalf of all member states; and hundreds of local prosecutors within each state (often referred to as district attorneys). Coordination among these many government actors is neither simple nor straightforward in America.

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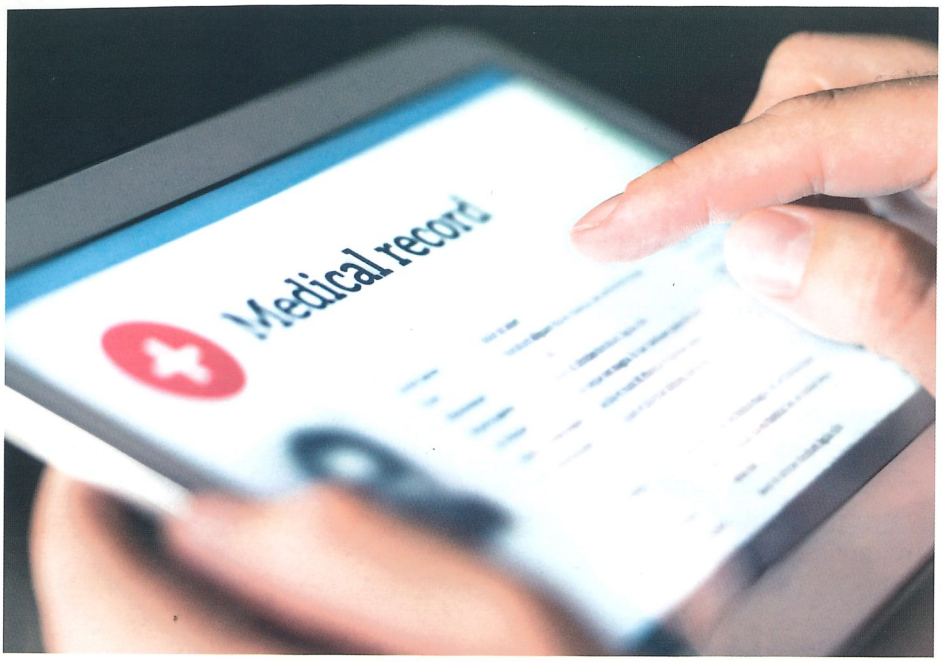
Although these federal and state law enforcement agencies often bring separate cases, their efforts have become increasingly more aggressive and coordinated. For example, in July 2017, the Department of Justice announced the results of the National Healthcare Fraud Takedown, which was the largest ever healthcare fraud enforcement action.[16] 412 defendants from across 41 federal districts were charged, including 115 doctors, nurses, and other licensed professionals.



The alleged fraud schemes totaled approximately $1.3 billion in false billings to federal and state agencies. Thirty state Medicaid Fraud Control Units also participated, and the Office of Inspector General initiated suspension actions, which are aimed at suspending the licensed providers' entitlement to receive reimbursement from federal or state agencies, against 295 providers, including doctors, nurses, and pharmacists. Coordinated government "takedowns" dramatically demonstrate the escalating coordination among American federal and state law enforcement agencies.

Private healthcare insurance enforcement

The second part of the American healthcare enforcement team comprises the fraud investigations and monitoring departments of large private insurance companies. Often staffed by former law enforcement professionals, private insurers often employ sophisticated claims analysis and medical chart reviewers to identify outliers or anomalies in healthcare claims data submitted to insurers. While private insurers are often more proactive than government payers, they cannot institute criminal fraud prosecutions. As a result, they frequently refer cases of suspected fraud to United States attorneys and state attorneys general for investigation and prosecution. Additionally, private insurers frequently make repayment demands from healthcare providers and will pursue providers civilly to recover funds for improper healthcare claims. Providers and manufacturers that operate in America would be wise to take seriously private insurance company audits and investigations because a small matter indicated by a case regarding a private health insurer can easily evolve into a full-blown federal or state criminal and/or civil fraud investigation.

Whistleblowers and their private lawyers

The third part of the American enforcement team are individuals—private-citizen whistleblowers also known as relators. Their role in combatting healthcare fraud in America over the past 30 years is unprecedented and increasingly critical. While members of the public are frequently told, "If you see something, say something," the reality is that private citizens loathe blowing the whistle on suspected fraud. Many would-be whistleblowers are loyal employees who first attempt to correct suspected problems internally. For many, it is simply easier and more career-friendly to turn a blind eye rather than get personally involved and risk retaliation at work.

This plagued the American healthcare system, at least until Congress amended the Federal False Claims Act (FCA) in 1986. Through changes in the law, Congress deputized citizens, with the help of their private counsel, to file lawsuits on behalf of the government against anyone who presented, or caused to be presented, a false or fraudulent claim for payment to the United States. These amendments created a sea change in enforcement for federally funded healthcare programs like Medicare and Medicaid. The FCA now also contains robust anti-retaliation provisions designed to protect whistleblowers.

These private-citizen whistleblower lawsuits are called qui tam actions, after the Latin phrase "**qui tam** pro domino rege quam pro se ipso in hac parte sequitur," meaning, "he who sues in this matter for the king as well as for himself." The person can be an individual or a corporation (e.g., competitor). Corporate and competitor qui tam suits are on the rise, perhaps in response to insidious large-scale fraud plaguing the industry.

In general, the qui tam provisions in the FCA permit any private person or entity to file an FCA case on behalf of the government. Whistleblowers do not need to be United States citizens or even live in the United States. They can live or work anywhere in the world, including Italy. Primarily, the whistleblower must have specific, credible information that the defendant presented false or fraudulent claims for payment of US government funds. Given the global impact of US government spending, the number of qui tam lawsuits filed under the FCA by whistleblowers located outside of America has increased in recent years.[17]

Since the 1986 amendments, private whistleblowers have filed more than 7,600 qui tam lawsuits involving alleged healthcare fraud alone.[18] Recoveries from those lawsuits exceed $32 billion in federal taxpayer funds. Through the qui tam provisions in the FCA, the government can now reach every healthcare provider, hospital, manufacturer, and even private insurer whose products or services are funded by the Medicare and Medicaid programs.

Private-citizen whistleblowers uncover and report fraud schemes that otherwise would have gone undetected. Qui tam whistleblowers have exposed a wide array of illegal practices, such as bribes and kickbacks paid to physicians, illegal marketing of pharmaceuticals and medical devices, medically unnecessary services, and dangerous treatment within nursing homes. Moreover, qui tam whistleblowers come from every level of a healthcare entity (e.g., the board room, the c-suite, the emergency room, or sales and marketing teams). As a result, the FCA has been widely recognized as the US government's most effective tool in combatting fraud, waste, and abuse in the American healthcare system. CT

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Takeaways

- There is one major challenge confronting American and Italian healthcare systems—providing healthcare that is effective, innovative, devoid of fraud, and cost effective.
- In the prevention of fraud, waste, and abuse, the American healthcare system is a complex web of government agencies, private organizations, and individuals (whistleblowers).
- Foreign providers/manufacturers in America should take private insurance company audits and investigations seriously as they can easily lead to full-blown federal or state criminal and/or civil fraud investigations.
- Whistleblowers do not need to be US citizens or even live in the US; they can live or work anywhere in the world.
- Corporate and competitor qui tam suits are on the rise, perhaps in response to insidious large-scale fraud plaguing an entire industry.