LAW360 Healthcare Authority

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Drug Cos. Face Persistent Scrutiny Over Physician Kickbacks

By **Hannah Albarazi**

Law360 (June 10, 2025, 3:06 PM EDT) -- Dr. Paul Bellman, who has treated patients with HIV and AIDS in New York City since the 1980s, grew concerned by the new combination drugs Gilead Sciences was encouraging physicians to prescribe.

For decades, pharmaceutical companies have argued that their lavish speaker programs serve to educate doctors about their products. Prosecutors and whistleblowers, however, contend that these events frequently mask illegal payments to healthcare providers. (iStock.com/Ivan-balvan)

In the summer of 2016, he decided to do something about it and filed a whistleblower complaint, alleging the way Gilead promoted these drugs risked exposing some patients to unnecessary health hazards, such as kidney damage.

Nearly nine years later, in late April of this year, Bellman's complaint was unsealed and the U.S. Department of Justice announced **a $202 million settlement** with Gilead. The government alleged that from 2011 through 2017, Gilead paid over $20 million in speaking fees and millions more in lavish meals, alcohol and travel to induce healthcare providers to prescribe its HIV drugs, leading to what it said were fraudulent claims against federal healthcare programs.

The Gilead settlement is the second in less than four months under President Donald Trump, ending cases brought by prior administrations accusing drugmakers of illegally incentivizing prescriptions. In the early

days of the Trump administration, the DOJ reached a similar settlement with Pfizer Inc.

These settlements follow a Second Circuit decision that lowered the bar for False Claims Act whistleblowers, leading some former prosecutors to anticipate increased enforcement in this area.

In January, Pfizer Inc. **reached a nearly $60 million settlement** resolving claims stemming from conduct at Biohaven Pharmaceuticals before Pfizer acquired it for $11.6 billion in 2022.

Prosecutors alleged that, from March 2020 to September 2022, Biohaven violated the Anti-Kickback Statute by offering expensive meals, honoraria and other perks to induce healthcare providers to prescribe its migraine drug, Nurtec ODT.

Both Pfizer and Gilead's settlements resolved claims of Anti-Kickback Statute violations through alleged fraudulent prescription schemes.

Pfizer said in a statement to Law360 Healthcare Authority that the settlement "does not include any admission of liability or wrongdoing" and that it is "pleased to put this legacy matter behind us."

A Gilead spokesperson told Law360 Healthcare Authority that the company "has evolved and strengthened its compliance programs in recent years, reinforcing a more comprehensive commitment with enhanced standards and new leadership."

Upon announcing the deal, however, Gilead said it entered into the settlement agreement "to avoid the cost and distraction of potential litigation regarding this legacy compliance matter" and maintained that its HIV treatment speaker programs "have served to educate healthcare professionals about the appropriate use and benefits of these important medicines."

For decades, pharmaceutical companies have argued that their lavish speaker programs serve to educate doctors about their products. Prosecutors and whistleblowers, however, contend that these events, often held at upscale restaurants, frequently mask illegal payments to providers that inflate healthcare costs.

Settlements Mount

Various deterrent efforts over the years have seen, at best, mixed success.

In 2020, the U.S. Department of Health and Human Services Office of Inspector General took aim at the speaker programs, highlighting the inherent risks of this type of doctor remuneration. And in 2010, with the Physician Payments Sunshine Act, payments to doctors were required to be publicly reported.

But still the programs persist, and so do enforcement actions.

Settlements involving alleged speaker program payments have accumulated to over $2.2 billion since 2015, including a $900 million settlement payment by Biogen Inc. in 2022. Prior to the 2020 OIG alert, other major drugmakers like Teva, Novartis, Insys Therapeutics, Salix Pharmaceuticals and Daiichi Sankyo had reached similar agreements.

In the three years preceding the OIG's 2020 fraud alert, drug and device companies reported paying nearly $2 billion to healthcare providers for speaker-related services, ranging between $600 million and $700 million annually.

While these payments dipped during the COVID-19 pandemic in 2020, to less than $350 million, they have steadily climbed back, reaching over $400 million in 2021, over $500 million in 2022 and nearly $600 million in 2023, according to Law360 Healthcare Authority's review of Centers for Medicare & Medicaid Services data.

Legal and medical experts argue that these speaker programs drive up costs by promoting more expensive — and potentially unnecessary — prescriptions. They argue that instead of turning to drug companies' marketing programs, physicians should rely on unbiased medical information.

Jonathan A. Willens of Willens & Scarvalone LLP, who represented whistleblower Bellman in the Gilead settlement, said Gilead's alleged conduct was "particularly shocking."

Willens said that when Gilead paid doctors to switch their patients to expensive HIV medications like

Stribild, Genvoya or Biktarvy, "Gilead introduced new and often unnecessary risks, putting profits ahead of patients' health."

As part of the settlement, Gilead acknowledged paying physicians an average of $1,500 to speak at its "HIV speaker programs," often providing doctors with meals and alcohol at high-end restaurants, and with many of the doctors making multiple appearances at dinners.

Some "high-volume prescribers" received tens or hundreds of thousands of dollars from Gilead during the early to mid-2010s. One doctor who received over $300,000 from Gilead wrote prescriptions resulting in over $6 million in Medicare, Medicaid and Tricare payments, according to the settlement.

Questionable Deterrence

Whether these government enforcement actions and financial settlements truly deter the behavior remains a point of contention among legal and medical experts.

Dr. Aaron Mitchell, an oncologist and health services researcher at Memorial Sloan Kettering Cancer Center, suggested that drugmakers view financial penalties as "mostly just the cost of doing business."

"Clearly, the behavior patterns have continued," Mitchell told Law360 Healthcare Authority.

He added that physician acceptance of industry money for promotional activities raises serious issues of professionalism, especially given the availability of unbiased medical information from neutral sources.

Conversely, some former prosecutors maintain that enforcement actions have significantly altered drugmakers' marketing practices.

Gregg D. Shapiro, a former prosecutor now representing whistleblowers, noted that overt inducements like lavish trips, once common, appear to have largely ceased.

Li Yu, a partner at Bernstein Litowitz Berger & Grossmann LLP and a former assistant U.S. attorney, said he believes that qui tam settlements have changed how established pharmaceutical companies market their drugs. However, Yu cautioned that "the same likely does not hold for startup pharma companies, which have strong incentives to increase sales as quickly as possible to maximize their valuations as acquisition targets."

Yu pointed to Salix, acquired by Valeant Pharmaceuticals for $11 billion after "aggressive use" of speaker programs, as an example.

"If they can sell before their speaker program fraud is exposed, owners of pharma startups do not even have to pay the settlements," Yu said.

Salix struck a settlement to end those claims in 2016, more than a year after its acquisition by Valeant, since renamed Bausch Health.

Dr. Robert Steinbrook, an internal medicine physician and director of health research at consumer advocacy organization Public Citizen, expressed skepticism about the pace of industry change, noting that drug company profits often significantly outweigh settlement amounts.

Steinbrook also highlighted the rarity of criminal cases against drugmakers for kickbacks, suggesting that a greater willingness to pursue such prosecutions against drug companies and their officers could be a stronger deterrent.

Steinbrook found the Gilead case particularly "mind-boggling," expressing bewilderment at healthcare providers repeatedly attending dinners or educational programs on the same topic just to obtain meals and other perks.

"Anybody would know this was inappropriate if they thought for two minutes about what was happening," Steinbrook said.

It's also hard, Steinbrook said, to comprehend how "a sophisticated drug company with great expertise, with life-saving HIV drugs would engage in this sort of procedure, these sorts of activities, [and] would not have a compliance program that was robust enough to put the quash on this immediately."

Steinbrook stressed that patients being prescribed expensive brand name drugs, when there are less expensive alternatives that are equally effective and safe, drives up healthcare costs for everyone.

Medical professionals can stay up-to-date on the latest advancements by attending continuing educational offerings by accredited organizations, he said.

Mitchell, the oncologist and researcher at Memorial Sloan Kettering Cancer Center, said research also suggests that drugmakers tend to present only positive information about their products, not the drawbacks.

A Shifting Legal Landscape

The legal environment for such cases has also evolved in whistleblowers' favor in recent months.

In a significant ruling in December, the Second Circuit held in Camburn v. Novartis that False Claims Act whistleblowers are no longer required to detail specific quid pro quo exchanges.

The decision also adopted the "one purpose rule" for the Anti-Kickback Statute, meaning that if just one purpose of a payment was inducement, it could be deemed illegal.

This ruling could have far-reaching implications beyond sham speaker programs, potentially affecting other types of allegedly improper inducements, such as drug copay waivers, free services to hospitals, bonus rebates to pharmacies, or marketing payments to insurance brokers that steer beneficiaries toward specific Medicare or Medicaid managed care plans.

Attorneys representing clients in the healthcare space say the allegations and settlements involving Pfizer and Gilead raise significant compliance considerations for the drug and device industries.

Jeffrey S. Baird, chair of Brown & Fortunato PC's healthcare practice group, warned durable medical equipment suppliers to take the Gilead settlement as a reminder to diligently monitor compliance.

"Gilead's compliance program should have recognized the dangers of the HIV Speaker Programs long before the program veered out of control. A successful compliance program is one that is continuously monitored and updated," Baird, who represents a range of pharmacies, manufacturers and healthcare providers, wrote in a Medtrade article.

In a client alert, attorneys Noah C. Goldstein and Phoebe T. Clewley of Porzio Bromberg & Newman PC said the Pfizer settlement underscores the government's commitment to holding violators accountable in the medical and the pharmaceutical sectors, warning companies commercializing healthcare products to assess all of their activities for compliance risks.

They also highlighted issues from the complaint not directly covered by the settlement. These activities included Biohaven's alleged underreporting of speaker payments to CMS's Open Payments system and the provision of electronic health record software cost assistance.

While the Trump administration has pulled back enforcement in certain areas, such as white collar crime, former prosecutors-turned-whistleblower attorneys Yu and Shapiro anticipate more enforcement in this area.

Yu expects "managing federal spending on prescription drugs will remain a priority, and the recent Pfizer and Gilead settlements should encourage whistleblowers to step forward to report similar types of speaker program drug-marketing fraud."

Shapiro anticipates that the current administration, like those before it, "will continue to take action against entities that engage in fraud, waste and abuse" and sees achieving compliance as a relatively low bar: "The companies just can't pay kickbacks to physicians, and their communications need to be truthful and nondeceptive."

--Editing by Haylee Pearl and Alex Hubbard.