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New Focus of Inquiry Into Bribes: Doctors

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A long-running federal investigation into the orthopedic device industry's suspected kickback payments to hip and knee surgeons now has the doctors in the spotlight.

Having reached settlements with the five leading makers of artificial joints last year over the payments, the government has been focusing on the many doctors who receive money as the companies' paid consultants.

"We are going to be looking at those soliciting kickbacks," Lewis Morris, the chief counsel in the federal office that pursues civil complaints of [Medicare](#) fraud, told an audience of hundreds of doctors, company representatives and investors this month in San Francisco at the annual meeting of the American Academy of Orthopedic Surgeons.

The same message has gone out to health care lawyers attending legal education seminars in recent months and, directly from [Christopher J. Christie Jr.](#), the United States attorney in Newark, who is overseeing the investigation. Executives say Mr. Christie has addressed sales meetings of the five companies, which reached a settlement last fall to avoid prosecution on charges they had routinely paid illegal kickbacks to surgeons.

Mr. Christie said " 'I've dealt with the supply issue, now I need to deal with the demand issue,' " recalled Edward B. Lipes, the executive vice president in charge of surgeon relationships at the device maker [Stryker Corporation](#), the first of the companies to cooperate in the investigation, which began in 2005.

Although industry executives say they have heard that some doctors have received subpoenas, none have been publicly identified. "Our investigation is continuing into the conduct of individual surgeons," Michael Drewniak, the spokesman for the United States attorney's office in Newark, said Friday.

Mr. Drewniak declined to say whether any of the doctors had become targets of the investigation.

The government has not argued that any of the kickbacks led to unnecessary knee or hip surgery or maltreatment of any patients. Nor has it established a direct link to higher Medicare costs. Switching a patient from one company's device to another would not change the amount Medicare pays [hospitals](#) for an implant.

But kickbacks might raise the overall cost of health care. Doctors can be convicted of violating Medicare's antifraud statutes simply for submitting a bill for a procedure linked to a kickback, whether or not the procedure was necessary.

Besides [Stryker](#), the original targets of the investigation were [Biomet](#); DePuy Orthopaedics, a unit of the [Johnson & Johnson](#) Company; [Smith & Nephew](#); and [Zimmer Holdings](#). Those four agreed to pay \$310 million in fines to settle civil charges.

In December, two smaller competitors, the [Wright Medical Group](#) and [Exactech](#), received subpoenas, indicating that the government is intent on making sure that the entire major joint business — the \$6 billion core of the orthopedics industry — is playing on the same field.

From the government's perspective, the investigation has already been successful. Even before the settlements with the device makers, those companies and others had sharply curbed entertainment, travel payments and other practices the government regarded as possibly influencing doctor's medical decisions. And with the settlements, still tighter restrictions were forced on the companies.

To avoid prosecutions that could have threatened the companies' Medicare business — a crushing blow in a segment of the health care industry where the average patient is 68 years old — the device makers not only agreed to pay the fines but to operate for 18 months under stricter federal scrutiny than military contractors do.

Mr. Christie's appointed monitors, overseers whom the companies pay monthly retainers plus up to \$895 an hour, screen every payment the companies make to doctors who help with training or with developing new products.

Each company is required to develop and gain government approval of a "needs assessment" detailing every task for which it will engage doctors this year. The settlements also set a \$500-an-hour ceiling for most consulting agreements.

In addition, all five were required to disclose on their Web sites cash payments last year to each doctor or medical group they dealt with, as well as compensation paid each of them in the form of plane tickets, lodging, food and gifts.

The companies halted nearly all types of payments to doctors and many education programs while completing the needs assessment, including previously pledged support for groups like the American Academy of Orthopedic Surgeons.

Stryker and Smith & Nephew say they have received final approval for their 2008 assessments. Other companies are at various stages of getting their assessments approved.

For all the disclosures and scrutiny though, the details of the misconduct that attracted the Justice Department's attention remain murky.

The companies were allowed to deny any wrongdoing in the criminal and civil settlements they negotiated. The four that signed so-called delayed prosecution agreements — Biomet, DePuy, Smith & Nephew and Zimmer — have been promised that the criminal cases filed against them in September will be dropped a year from now if they live up to compliance procedures in their agreements.

No charges were filed against Stryker, the fifth company, because it was the first to cooperate in the investigation. But Stryker accepted the same restrictions on its conduct and was also assigned an independent monitor for 18 months. Stryker's potential civil liabilities were left unresolved.

The five companies' payment disclosure lists say nothing about what the doctors on them did to receive their money. As a result, there is no apparent way to distinguish potentially questionable kickback deals amid a

sea of service contracts, licensing agreements and research grants that the government agrees are legitimate.

The American Academy of Orthopedic Surgeons has said that the listings raise unfair suspicions and that the companies should provide more detailed breakdowns of the payments.

“A lot of this has been irresponsible,” Dr. Thomas M. Coon, a surgeon in Red Bluff, Calif., said of the government’s investigation during a break at the recent meeting in San Francisco.

Dr. Coon said the broad reach of the government’s action had “thrown up in the air” hundreds of company-surgeon relationships. “Who knows how it will come out?” said Dr. Coon, a pioneer in minimally invasive knee surgery, who has consulted principally for Zimmer, the largest hip and knee company.

Dr. Coon declined to say how much he was owed after Zimmer halted payments in October. Zimmer’s disclosure said it paid him \$158,420 last year — in addition to \$1,944 for air travel, \$2,498 for lodging, \$1,034 for meals, \$440 for ground transportation and \$10 for a gift.

Identifying any rogue surgeons could be politically sensitive for Mr. Christie, who has been reported to have aspirations to run for governor of New Jersey. He stirred controversy in Congress for appointing his previous boss, the former United States attorney general, [John Ashcroft](#), to the lucrative job of monitoring the activities of Zimmer, the largest implant company.

“They will probably find somebody to indict, but people are viewing the attorney general’s office with a lot of distrust,” said Dr. Robert H. Schmidt, an orthopedist in Fort Worth.

As indicated by Dr. Coon’s work with Zimmer, financial relationships between orthopedics companies and their customers are among the most complicated in health care. In contrast to drugs, which are typically developed in company laboratories, many orthopedic devices and related tools originate from inventions by doctors, who often retain a financial stake in their market success.

Once companies begin to develop the devices, leading doctors are hired as consultants to help modify the implants and related hardware. When the products are finally brought to market, companies also hire many of the same opinion leaders to train other doctors and sales representatives how to use them.

As a result, Mr. Christie has had no problem finding large sums of money — in some cases, more than \$1 million annually — flowing from companies to doctors who use their devices. But doctors say it is far too simplistic to conclude, as Mr. Christie claimed last fall, that “many orthopedic surgeons in this country made decisions predicated on how much money they could make — choosing which device to implant by going to the highest bidder.”

For the most part, the hip and knee joints sold by the major companies are similar in performance, but getting surgeons to switch is a lot more difficult than persuading an internist to prescribe a prescription drug rather than aspirin.

Familiarity with a joint and the tools to put it in place may be the single biggest factor in a surgeon’s success with a patient, according to Dr. Ronald P. Grelsamer, a Brooklyn orthopedist and author of books on hip and knee reconstruction.

“Surgeons are by and large reluctant to jump from one horse to another,” Dr. Grelsamer said.

As a result, surgeons would be looking to whatever cases might be brought against their peers to clarify the lines the government wants drawn between unacceptable and acceptable relationships with the device industry.

Mr. Christie and Mr. Morris, the top lawyer in the Office of the Inspector General in the [Department of Health and Human Services](#), will in turn face tough choices on how many cases to pursue. Complaints against individual doctors rarely have the impact on overall medical practice that cases against large companies or groups of companies do, nor do they produce large financial compensation for the government.

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