Federal prosecutors have set their sights on the pharmaceutical industry. By the end of 2001, virtually every major drug company will have received grand jury or other subpoenas in ongoing criminal and related civil investigations. Significantly, these companies will confront a far larger federal enforcement team than existed a decade ago. Since the early 1990s, the number of federal prosecutors devoted to healthcare fraud has increased fivefold, while the number of FBI agents working healthcare fraud cases has tripled during the same period. These prosecutors and agents have generated three times as many federal criminal and civil healthcare fraud cases since 1993. Just since 1996, the Department of Justice has recovered close to $3 billion in criminal fines, restitution, and civil recoveries. The amount of criminal and civil fines imposed by state prosecutors and regulators, and the number of lawyers and agents devoted to these investigations, has also increased significantly since the early 1990s.

Over the past decade, these resources were brought to bear first on the clinical laboratory industry, resulting in billions of dollars in fines, and then on the major hospital chains. Now it’s the pharmaceutical industry’s turn. And given the increasing publicity and debate over rising prescription drug costs, prosecutors likely will be demanding billions of dollars in settlements. One prosecutor investigating the pharmaceutical industry was quoted recently as comparing the industry to the defense industry in the late 1980s, which faced dozens of federal criminal investigations and paid billions in fines during this period.

The current cases against the pharmaceutical industry can be divided into four principal categories, each involving a slightly different pricing or marketing practice.

**AWP Investigations**

First, federal and state prosecutors have launched a series of investigations involving the average wholesale price (AWP) reported by drug manufacturers. Under the Medicare program, the federal government reimburses physicians for the few medications covered by Medicare (mostly injectable medications administered in physician offices) at ninety-five percent (95%) of the AWP, which is not defined by statute but is reported by the companies in industry publications such as the *Red Book*. According to the government, certain pharmaceutical companies have marketed drugs to physicians by advertising the “spread” between what the physician can receive in reimbursement (95% of an allegedly inflated AWP) and the much lower price that it will cost the doctor to actually purchase the drug before dispensing to the patient. Documents produced to a House Committee last year revealed that physicians were purchasing certain drugs for $4 and $5 yet those medications had published AWPs above $30. The HHS Inspector General’s office estimated recently that the Medicare and Medicaid programs may be shortchanged by as much as $1 billion annually by alleged misreporting of AWPs.

Last year, the media reported that more than 20 companies were being investigated for allegedly reporting inflated AWP prices on drugs used to treat AIDS and cancer. According to the government, these companies may have “caused” a “false claim” to be submitted to Medicare (or Medicaid, which also uses the AWP concept) by publishing allegedly inflated AWPs while “marketing the spread” to doctors. This conduct is alleged to violate the False Claims Act and other federal civil and criminal laws.

One problem the prosecutors may confront in these AWP cases is that government officials have known for a long time...
that the reported AWPs are not based on real-world purchasing data. Indeed, the Department of Health and Human Services (DHHS) acknowledged more than 20 years ago that AWPs “often are not closely related” to the drug prices actually charged to private providers such as pharmacists and doctors. In 1989, the DHHS Inspector General published a study demonstrating that many pharmacies were purchasing brand name medications at 15% below the published AWP figure. A more recent study reported that the gap between published AWPs and many real-world purchasers had increased to 22%. If the government presses forward with these cases, and a defendant company seeks to contest the charges, the “government-knew-it-all-along” argument may have some appeal to courts and juries.

Earlier this year, Bayer entered into a $14 million settlement of these AWP allegations. As detailed in a corporate integrity agreement, Bayer must submit quarterly sales reports detailing its “average sales price” (a new term, defined in the agreement) for government-reimbursed drugs to the DHHS/IG and state Medicaid agencies. The government announced that the agreement would “facilitate” the establishment of “fair reimbursement rates” for many pharmaceuticals (not just Bayer products), but notably the agreement does not define AWP or even identify the government’s expectations of how to report AWP. Bayer also agreed to appoint an internal compliance officer and create a compliance committee to monitor Bayer’s day-to-day compliance with the relevant laws and regulations.

Prosecutors will likely assert that the Bayer settlement should set the floor, rather than the ceiling, for subsequent AWP settlements, although many of the drug companies may have powerful arguments as to why the allegations against Bayer should not apply to them. The Bayer settlement also has been criticized by the defense bar for leaving the AWP issue as muddled as ever, with additional legal vulnerability for Bayer through the submission of these quarterly reports. Still, it is likely that prosecutors will expect large dollar settlements and Bayer-type corporate integrity agreements across the industry.

**Best Price/Repackaging Investigations**

A second set of cases, pursued by both federal and state prosecutors, involve two related issues under the Medicaid prescription drug program. Under this program, drug companies wishing to qualify their products for Medicaid reimbursement must enter into rebate agreements under which the government is entitled to the greater of (i) a 15.1% discount off the “average manufacturer’s price” or (ii) the difference between the AMP and the “best price” for that drug, defined as “the lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, or [HMO].”

In the past year, federal and state prosecutors have commenced investigations of several companies for allegedly underpaying the government rebate by failing to report certain drug sales offered to particular customers. For example, prosecutors allege that sales to HMOs represent a discount that should be listed as the “best price” from which the government rebates should be calculated. Prosecutors also allege that the Medicaid rebate provisions have been circumvented by a practice known as “repackaging,” in which certain drug companies sell pharmaceuticals in bulk to HMOs, which then repackage the bulk drugs with their own labels and in smaller doses and resell them to network doctors. Prosecutors allege that the government should get the benefit of these allegedly “best price” deals. Finally, the
government is examining whether in-kind benefits, such as educational grants and disease management programs, offered to drug company customers should be considered price discounts or rebates, and if so, whether those discounts should be included in the Medicaid rebate calculations.

The government’s theory appears to be that the drug companies may cause or otherwise facilitate the filing of a false or inflated claim by not including the lowest-price deals (however defined) as part of the Medicaid rebate calculations. Potential statutes under which the government may proceed include the False Claims Act and the Anti-Kickback Act.

**Physician Inducement Investigations**

Another set of investigations, run largely by the U.S. Attorney’s Office in Boston, focuses on whether certain companies (such as Bristol-Myers and TAP) gave treating physicians certain inducements (like free drugs and medical devices) to prescribe or administer that company’s products, with the resulting higher Medicaid and Medicare reimbursement for the physician. Several physicians have already been indicted in these cases, and pharmacy directors, hospital personnel, and potentially pharmaceutical company employees may be the next target of federal criminal indictments. Abbott Laboratories, which owns half of TAP, said recently it has earmarked close to $350 million to settle this case. Other companies can expect similar investigations, which may strike at the heart of many of the industry’s customary physician marketing practices.

**PBM Investigations**

The U.S. Attorney’s Office in Philadelphia has launched an investigation into allegations of possible collaboration among drug makers, pharmacy benefit managers (PBMs), pharmacists, and physicians. In particular, the government is examining the process by which PBMs, which operate many of the large pharmacy benefit programs for government and private insurers, place prescription drugs on their formularies and those of many large health plans. The prosecutors running these cases assert that drug companies have been offering inducements to physicians and pharmacists in an effort to get their drugs placed on the formulary, allegedly without regard to cost or clinical necessity. As with the “best price” investigations, it is not just the obvious discount or rebate to get medications on the formulary that is drawing federal scrutiny—in-kind benefits such as staff, computer programming software, and other disease management program benefits are also being examined to determine the extent to which they may influence placement of a potentially higher-priced drug on the formulary. According to the prosecutors, some or all of these practices may implicate the Anti-Kickback Act, which has both civil and criminal penalties.

**Conclusion**

This focus on the pharmaceutical industry and its marketing practices is only going to intensify. In all likelihood, more federal prosecutors and agents will become involved as they become conversant with industry practices and the reimbursement process. State prosecutors, assisted by the very able state Medicaid Fraud Control Units, are becoming increasingly active in this area, with prosecutors from Texas, Florida, and Massachusetts issuing subpoenas and questioning witnesses. Pressure to bring indictments and seek civil fines also may intensify as Congress debates and at some point enacts a comprehensive prescription drug benefit for Medicare beneficiaries. The debate over this legislation, and the ever increasing cost for prescription drugs, will keep these cases on the front burner of the nation’s prosecutorial agenda for years to come. 

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**DIETARY SUPPLEMENTS**