Stark Law and Pharmaceutical Company Kickbacks

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What do Lance Armstrong and pharmaceutical scandals have in common? More than you would think.

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This week, Lance Armstrong desperately fought to preserve his “Livestrong” Foundation after details emerged of an illegal blood-doping scheme, which resulted in the erasure of his seven Tour de France championships.

Lance Armstrong’s downfall, though tragic, provides an excellent starting point for a three-part series studying the ethics of gift-giving schemes and the consequences under federal, civil, and criminal law, in the event your practice should consider accepting illegal gifts from drug companies, medical device manufacturers, home health companies, and others.

Exactly how do Lance Armstrong’s blood-doping problems relate to your practice? The answer as it turns out, is “quite a bit more than you might think.”

In the 2011 documentary novel by Kathleen Sharp, “Blood Feud: The Man Who Blew the Whistle on One of the Deadliest Prescription Drugs Ever,” (New York: Penguin Group Publishing) the book’s author exposes the dark side of pharmaceutical marketing. “Blood Feud” is a behind-the-scenes true account told from the perspective of Mark Duxbury, a fresh Johnson & Johnson drug representative who was given the task of selling the new anemia drug “Procrit” to physicians and hospitals in the Pacific Northwest.

Sharp details how in 1981 the tiny biotech firm, Applied Molecular Genetics (Amgen), isolated and synthesized human erythropoietin (epo) — a hormone naturally produced by the kidney which stimulates the production of red blood cells. Although according to Sharp, Amgen had created the world’s first big genetically engineered drug, Amgen was also strapped for cash from the lengthy FDA approval process. In 1989, Amgen practically gave the patent away when it sold a huge (but ill-defined) share of the marketing rights to Johnson & Johnson.

Because market share in the simple five-page contract was poorly worded, a battle for market share ensued between partners who were selling identical drugs: J & J’s “Procrit,” and Amgen’s “Epogen.” Sharp describes how Duxbury’s bosses soon demanded that he steal Amgen’s clients, by offering illegal (but cleverly hidden) 8 percent kickbacks and thinly disguised “research” grants to physicians and hospitals, which were designed to win patronage through perverse incentives. Sharp then details how much to the surprise of both Amgen and J & J, professional bicycle racers (apparently including Lance Armstrong) began acquiring illegal supplies of Procrit and Epogen to cheat in bicycle races. If the story isn’t seedy enough, it gets much worse. Sharp also recounts Duxbury’s shock at the realization that veterinarians had begun writing J & J to claim an 8 percent bonus for injecting race horses and dogs with Procrit. In order to understand just how bad this is, we need to unpack this.

Veterinarians were: 1.) illegally injecting animals with human epo hormone; 2.) allowing criminals to illegally cheat on gambling activities; then 4.) were claiming the illegal 8 percent kickback for illegally prescribing a human drug to animals, in order to illegally cheat on racing.

Amgen, for its part, allegedly had a much more clever way of offering kickbacks to physicians. Amgen allegedly began overfilling single-dose vials of its drug, then encouraged doctors to harvest the overfill. Amgen internal marketing documents show that the company encouraged doctors to bill the government as if the doctors had actually paid for the harvested dose (which would be a form of kickback.)

Although Amgen recently set aside nearly $1 billion to settle state and federal whistleblower lawsuits, it has appealed the whistleblower cases to the United States Supreme Court. An excellent brief (written in opposition to Amgen by a retirement fund in support of the plaintiffs) details the systemic fraud allegedly perpetrated by the pharmaceutical industry.

Although the federal regulations on accepting gifts can be quite confusing, physicians may fairly well steer clear of all federal offenses by simply adhering to a few rules contained in the AMA Code of Medical Ethics.
Next week, we will discuss what those rules are.