

Conflicts of Interest and Double Standards

Why was Jay Yadav, MD, dismissed from the Cleveland Clinic?

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Many of you must be puzzled with the recent news regarding Dr. Jay Yadav, one of the most respected interventionists in our field, being terminated from the Cleveland Clinic Foundation (CCF). To be precise, he was not fired, but his annual contract was not

renewed without cause or warning, and I think it is fair to say that for all practical purposes, he was fired. This comes to many as a big surprise because he received an endowed chair 2 months earlier, and he was appointed as the Chairman of the Department of Innovation at CCF 8 months prior to that.

In discussing a matter that is entirely predicated on disclosure of conflicts of interest, I should disclose my own: Jay Yadav is not just a gifted interventionist and colleague; he is also a friend whom I greatly admire and respect, as well as a pioneer in the field of endovascular therapies, and for that I am both indebted to him and saddened by this recent turn of events. Finally, for the sake of completeness, it may be appropriate to disclose the fact that Jay Yadav is one of the founders of CardioMems, Inc. (Atlanta, GA), and I am a consultant for this company.

We all may take carotid stenting for granted, but it all started when Dr. Yadav initiated an investigational program at the University of Alabama in 1993. He had just finished a neurology fellowship and, during that period, he thought that there had to be a better way than surgically removing the plaque to treat patients with carotid stenosis who were poor candidates for carotid endarterectomy. He thought about stenting the lesions and joined Dr. Gary Roubin, the Chief of Interventional Cardiology at the University of Alabama at that time, and completed general and interventional cardiology fellowships. He created a porcine model of carotid stenosis and then developed a protocol for carotid stenting. He later developed the first filter-based brain protection device, which was the key tool in making carotid stenting a viable alternative to carotid

endarterectomy. Finally, he conducted the landmark randomized trial (SAPPHIRE) that, for the first time in history, validated the safety and efficacy of carotid stenting.

Although CCF has not publicly stated the precise grounds for firing Dr. Yadav, one can speculate based on some facts. In a statement released on August 18, 2006, CCF stated that Dr. Yadav had lost his position as part of a larger process of refining their conflict of interest processes. "The Board of Governors of the Cleveland Clinic on August 18th took action not to reappoint Jay Yadav, MD, to its medical staff," the statement reads. "He is no longer at the Clinic. As an institution, we will continue to strongly encourage innovation while eliminating and managing conflicts." The implication from this statement is clear that Dr. Yadav was fired because of issues related to conflicts of interest. A comprehensive exposé in *The Cleveland Plain Dealer*¹ outlined the events that led to Dr. Yadav's dismissal. According to the article, Dr. Yadav's dismissal centered on his failure to disclose an alleged "royalty fee" that he has continued to receive from Cordis/Johnson & Johnson (Miami, FL) on sales of AngioGuard devices.

As a physician/investigator/investor myself, and more importantly, as someone who has great respect for Dr. Yadav and his contributions to endovascular medicine, I feel compelled to speak out.

Let me discuss the facts as I view them. According to *The Cleveland Plain Dealer*, Dr. Yadav failed to disclose to CCF and the public that he was receiving a royalty fee from Cordis Corporation. Dr. Yadav had originally invented the device, founded the company that developed the device, and owned shares in AngioGuard, Inc., which was sold to Johnson & Johnson in 1999 for approximately \$40 million. These alleged "royalties" were actually described as a "deferred payment" in the deal. ("Royalty," a legal term with numerous definitions, is ordinarily a payment to the owner of a patent such as an inventor for the use of his invention. A deferred payment is simply delayed payment of some portion of the purchase price for the sale of a business made at some interval in the future. The definitions likely overlap somewhat, and the differences are complex legalities. The point here is that Cordis, which drew up the documents, calls

the small residual payments that are tied to patent infringements and global sales 'deferred payments,' and that is exactly how Dr. Yadav disclosed them). The fact is that all AngioGuard shareholders were receiving deferred payments as part of the sale of the company. These payments were *pro rata* for their shareholdings, and the total of all such payments made to all of the shareholders since the sale in 1999 amounted to approximately 2%, or a tiny fraction of the total consideration. The payments from Cordis, while related to AngioGuard's patents, as well as its revenues, are clearly labeled as deferred payments.

Now, let's use some common sense. Dr. Yadav is a well-respected clinician and entrepreneur who held a Chairman position and endowed chair at a world-recognized institution. These positions were all obtained after the well-known sale of Angioguard, Inc. in 1999. It defies common sense that a man so successful and a person who had always been upfront about his relationship with AngioGuard would intentionally hide such a relatively small amount of money, and what can only be described as *de minimis* continuing payments after the sale of AngioGuard, or that CCF would not know about it until 2006.

The *Cleveland Plain Dealer* article notes that the "royalties" are tied to the sales of the device. However, the device was not yet available for sale in the US and, therefore, this arrangement with Cordis did not create a conflict with his patients or with CCF (Cordis announced FDA approval of the device on September 26, 2006). The *Cleveland Plain Dealer* does not make clear whether Dr. Yadav made appropriate disclosures in association with the SAPHIRE study in which he served as Principal Investigator. Based upon documents I have had an opportunity to review, Dr. Yadav had disclosed the details of the transaction, including the deferred payments, to CCF in writing in 2001. The ongoing financial interest in the marketing of the device was disclosed to the FDA in 2003. The ongoing proprietary interest in the device was also disclosed in subsequent studies involving the device in 2005. Thus, where is the intent to obscure, cover up, or mislead CCF or the public on his continued interest in the success of the device?

I have attended many, if not most, of the medical conferences at which Dr. Yadav has given lectures related to carotid stenting since 1996. Since Cordis acquired AngioGuard, Inc. in 1999, he has always disclosed (both verbally and in writing) the fact that he was the inventor of this device and the founder of the company, with significant financial interests. I have heard it hundreds of times, and I know that I am not the only one. Frankly, I doubt that anyone who has used AngioGuard is unaware of Dr. Yadav's connection and contribution—each and every package for AngioGuard says, "Based on the ideas of Jay Yadav, MD"—and he has always been up front about this. In fact, it is fair to say that Dr. Yadav led us and taught us about how to handle conflicts of interest, something that was new to

many of us at that time.

Our legal and ethical system is such that mistakes and crimes are punished proportionally to their consequences and presence or absence of intent. Apparently, after well-publicized issues pertaining to CCF's conflict of interest policy, a new Web-based disclosure procedure was created. Beginning in 2005, CCF physicians no longer created paper disclosures, but rather recorded any actual or perceived conflicts of interest electronically through a series of questions and yes/no responses which, depending on the response, prompted further disclosure. As I understand it, all corporate affiliations of Dr. Yadav were disclosed, but apparently, the electronic disclosure did not properly or completely respond to the inquiry of "royalties," although these disclosures had been made in written form 4 years earlier. Thus, with the stroke of a mouse click, the reputation of a world-renowned cardiac interventionist was tarnished. If Dr. Yadav committed an oversight on some recent disclosure form, what were the consequences of Dr. Yadav's unintended oversight? Were treatment patterns changed? Were patient lives affected? Were any decisions made that would have been made differently if Dr. Yadav's Web-based disclosure at CCF mirrored his written disclosures in 2001? Just recently, on September 26, the FDA approved AngioGuard's use in the US. Would that decision have been otherwise? I doubt it—in light of the prior disclosure to the FDA of his ongoing interest in the marketing of AngioGuard.

I find CCF's treatment of Dr. Yadav particularly disturbing because the Clinic and its senior personnel have been widely reported² to have far more consequential conflicts. Is Dr. Yadav simply being made the fall guy for perceived past institutional transgressions?

Of course, conflicts of interest are a very important issue facing physicians, hospitals, and the entire medical device industry. It is imperative to the public's trust in the medical system that we remove conflicts of interest whenever possible and disclose them in those situations in which removing the conflict is either impossible or impractical. However, while we pursue this noble goal, we still need to exercise common sense, fairness, and justice. ■

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1. *Cleveland Plain Dealer*, September 18, 2006.

2. Armstrong D. How a famed hospital invests in device it uses and promotes. *Wall Street Journal*, December 12, 2005, p A1.