Our JAMA Paper on Industry Payments and Sowell's Conflict of Visions

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MAR 31, 2024

My career in cardiology can be separated into two decade-long blocks.

The first decade I practiced like most other cardiologists. I went with the flow, followed the guidelines. I went to few meetings, read few studies and as a result had little (mental) tension.

Then I started writing about medical evidence. This required studying the evidence. Over time, I learned the skill of critical appraisal. Cardiology practice got a lot harder.

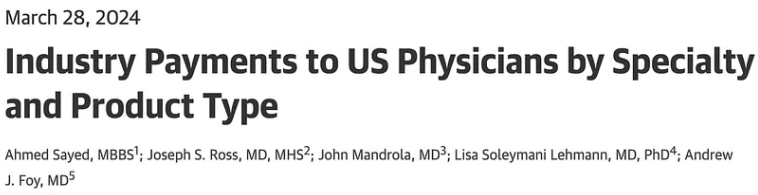
One example: almost a decade ago, my editor asked me to look into left atrial appendage occlusion. Whoa. There were two seminal trials. One did not pass FDA muster due to internal validity issues. The other one failed to meet its lax noninferiority primary endpoint. No matter. FDA approved the procedure, and BOOM, it is now a hugely popular and lucrative procedure.

As I walk through the hospital these days, having looked at the actual evidence for what we do, my brain struggles to resolve the tension between the popularity of treatments vs the dubious evidence.

So. When Ahmed Sayed and Andrew Foy asked me to participate in a research project looking at industry payments to doctors I was happy to help. This data, I thought, might

help explain the tension between the often shaky evidence and popularity of procedures.

The influential *Journal of the American Medical Association* published our data this week. The numbers surprised me.



March 28, 2024

Industry Payments to US Physicians by Specialty and Product Type

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Our main finding was that industry paid doctors more than $12 billion dollars between 2013-2022. B as in billions.

We could know these numbers because of the Open Payments web platform wherein any payments to doctors from industry must be declared. We then linked this data to another database called the National Plan and Provider Enumeration System—which provided more granu

We excluded researc plies and devices. Our data entertainment, educa

Here are the main fin

- 57% of doctors r
- the median payr e associated with a
- A small number g $1 million, while the
- Orthopedic surg ogists and psychiatrists at $1.32 billion, and then cardiologists at $1.29 billion.

- Within each specialty, payment distributions were skewed, with payments to the median physician ranging from $0 to $2339, whereas the mean amount paid to the top 0.1% of physicians ranged from ≈ $190K for hospitalists to more than $4.8 million for orthopedic surgeons.
- The 3 drugs associated with the most payments were rivaroxaban (Xarelto) at $176 million, apixaban (Eliquis) at $102 million, and adalimumab (Humira) at $100 million. Right behind these were the SGLT2 inhibitors empagliflozin and dapagliflozin.
- The 3 medical devices associated with the most payments were the da Vinci Surgical System ($307 million), Mako SmartRobotics ($50 million), and CoreValve Evolut ($44 million).
- Other cardiology devices that made the list were Sapien 3 (TAVR), Impella (ventricular assist device), LifeVest (wearable defibrillator), Watchman (left atrial appendage occlusion), and MitraClip (mitral valve repair).

Our paper is a modest analysis. It does not explain the problem of financial conflicts of interest. But it is a lot of money. And it's highly targeted to lucrative procedures.

Let me make two points. First, you should read Dr. Sanjay Kaul's recent essay on the difference between drug and device FDA approval. His list of device approvals despite dodgy evidence is shocking. I made this slide summarizing most of the devices Kaul mentioned:

Dubious Evidence for Devices

MitraClip	Mitral valve repair	Approved yet 1 trial (industry funded) showed benefit, but a similar trial (gov't funded) showed no benefit
CardioMems	HF monitoring	Expanded indication despite negative trial—turned "positive" with a post-hoc subgroup analysis
Watchman	LA appendage plug	Approved despite a regulatory trial (PREVAIL) that failed to show noninferiority in co-primary endpoint
IMPELLA	LV assist device	Approved despite regulatory trial vs balloon pump stopped for futility. IABP previously shown non-beneficial
Resorbable stent	Coronary stent	Approved based on non-inferiority but later recalled due to harm
PFO closure	Stroke prevention	One of the regulatory trials was non-signif. Approval based on a total of only 25 events
Renal denervation	Hypertension Rx	Approved with minimal to no sham-controlled significant BP reductions over only 6 months

Cardiology is a technical field. We use devices. Innovation requires *some* collaboration. Innovation has made cardiology better.

But industry influence is way too strong. How else would the devices above become accepted?

Here is one theory: The monies we report in this paper are not only for MD-industry collaborations. Most of it, I would argue, is for marketing and goodwill.

Goodwill goes a long way to help establish practice patterns.

When an industry rep brings lunch for the cath lab, the problem is not that the doctor gets a $20 free lunch; the issue is that the free lunch a) provides goodwill (e.g. the nice company brought the staff lunch), and b) the rep now has time to tell everyone what's going on that big meetings and across town at the competing hospital. (e.g. *Those docs love our device*.)

The ultimate goal of industry is profit. That's not nefarious. But. Since industry is profit-driven, they spend money wisely. Money given to doctors has a purpose: it is for marketing. Much as an advert is in a scientific journal, a speakers fee is an advert.

If these direct payments to doctors did not work, industry would not spend billions.

Second point. Co-author Andrew Foy and I talk often about the Thomas Sowell book Conflict of Visions. In brief, Sowell described a constrained and unconstrained view of human nature. Unconstrained thinkers believe in ideal solutions; we can make a perfect society. Constrained thinkers believe that human nature is unchanged, cannot be modified and decisions must therefore always consider tradeoffs.

Now apply that frame to medicine.

Unconstrained thinkers dominate medicine. More is better. We can solve human disease. We just need to do more tests, give more drugs, keep innovating. Everything is modifiable. *(Think, total body MRIs.)*

Foy and I are constrained thinkers. We appreciate true progress (antibiotics, pacemakers, insulin, and even stents for acute MIs), but we hold a much more conservative view of many of the "new" developments. Tradeoffs seem more obvious to us. We see harm in wasting money on marginal devices. We accept the role of chance in survival.

Now back to our paper.

The reason the unconstrained vision dominates in medicine is industry influence. The nanosecond you walk into a major medical meeting, it's obvious that constrained thinkers don't have a chance.

Industry money and the influence it brings provides the tailwind for unconstrained thinking. Constrained thinkers can get labeled as nihilists or scolds. Constrained thinkers don't give plenary sessions.

I like my role outside of industry influence. But I am old and in the later innings of my career. The challenge is how to bring constrained thinking to younger doctors. One way is to limit industry influence. Let me know if you have other ideas.

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