ADVANCED MEDICAL STRATEGIES

Predicting costs. Managing claims. Empowering users.

THE BIG SCREW:

How Manufacturers, Insurers, Providers, PBMs, and the Government Are Keeping Us in the Dark

- **The healthcare industry is rife with secrets**
- **Drugs and device efficacies are elusive**
- **Prices are kept opaque**
- **Payers/patients lack clarity**

Someone got screwed. I mean that literally, though not in *that way*.

I have a patient's itemized bill in front of me which lists the price for a single screw used in his spinal implant surgery: $12,291.00. Sound like a lot? It is. Not that he would know.

But then there's this: his insurer doesn't know either. It's a mystery to them, too. Medical-surgical implants and devices are a black box in the healthcare industry. Sure, the hospital knows what they paid for the screw, but they're not obligated to report that amount to anyone. So, they don't. And the manufacturer sure isn't telling.

Drug costs aren't as opaque. There are a few benchmarks to go by if you know where to find them. But not many people would know where to look for those either. Besides, by the time patients have to pay for their pharmaceuticals there's been so many confidential backroom deals made throughout the pipeline it's nearly impossible to tell if they're getting a good price.

Healthcare as a concept is very personal for most Americans. Rules and regulations surrounding patients' privacy are of paramount importance. These protections exist to safeguard people from fraud and exploitation when they're at their most vulnerable. As a whole, the healthcare industry has appropriated that concept of privacy for themselves. And not in a good way. Whenever the topic of transparency rears its ugly head the industry players fiercely band together to preserve their clandestine confidentialities. (Then it's back to loudly blaming each another about obfuscation and price gouging!)

Have Questions? Contact Stephanie Belschner at 781.224.9711 Ext. 116 or sbelschner@mdstrat.com today to get started.

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How Does the Industry Deceive Thee?
Let Me Count the Ways.

Manufacturers

One word: collusion. In a report from NPR, "forty-five states and the Department of Justice are claiming that generic-drug prices are fixed and the alleged collusion may have cost U.S. business and consumers more than $1 billion." [1]

There's collusion among makers of branded-drug as well. An Advanced Medical Strategies blog article about Insulin [2] described its long legacy of price fixing among manufacturers:

> [From] the time Novo Nordisk's Levemir came on the market in 2001 to compete with Sanofi's long-acting insulin, Lantus, until 2015, the prices and corresponding increases between the two had been nearly identical. Similarly, Lilly's insulin Humalog and Novo Nordisk's Novolog to this day have been in lockstep since 2001. Many have raised their eyebrows concerning such timing and pricing parallels. Industry reps have brushed off such accusations as mere market forces at work. (Cynics would say their reputations precede them, pointing back to 1941 when Lilly and two other pharmaceutical companies were indicted for an alleged insulin price-fixing scheme, and in 2010 when Lilly and others were fined for collusion re insulin pricing.)

Drug manufacturers are notorious for raising drug prices—especially specialty pharmaceuticals—astronomically over the years. That's no secret. However, Big Pharma contends that if they charge less for pharmaceuticals then their manufacturing and R&D will be stifled. This is a well-worn scare tactic, revealed as fallacy merely by taking a peek at their own financial reports. A look at 13 major pharmaceutical companies from 2011-2017 reveals that "the total amount they spent on marketing was about 60% more than what they spent on research... they also made more in profits each year, on average, than they spent on research." [3]

Proportional Allocation of Revenue
2011-2017

Courtesy of David Belk MD/trucostofhealthcare.org

That's what we can see from their financials. What we can't see was the subject of a recent report from the poverty and injustice organization Oxfam. Their investigation revealed "the size and scope of the tax dodging by some of the world's biggest pharmaceutical companies... Oxfam scoured the corporate balance sheets of Johnson & Johnson, Pfizer, Merck & Co. and Abbott in 20 countries and uncovered alarming new evidence that these corporations appear to be using offshore tax havens to dodge billions of dollars in tax." [4]

Oxfam takes pains to note that these companies are not doing anything illegal. However, in light of their shady dealings Oxfam calls them out "to release basic financial information, like revenue, profits, taxes paid, assets, and number of employees, in every country in which they operate." Oxfam's moxie is commendable, but one tends to think these documents will continue to stay under wraps.

If manufacturers aren't playing financial hide-and-seek they're snuffing out competition with legalese. Branded drug makers often abuse patent extensions and exclusivity rights (aka "evergreening" or "product-hopping"), and even pay generic drug makers not to bring cheaper options to the market ("pay-for-delay"). [5] "Let's not forget

1 https://www.npr.org/2018/03/07/590217561/probe-into-generic-drug-price-fixing-set-to-widen
2 https://www.mdstrat.com/insulin
3 http://truecostofhealthcare.org/the_pharmaceutical_industry/
4 https://www.oxfam.org.nz/blogs/2018/09/18/revealing-big-pharma-s-tax-dodging-story-behind-numbers
5 https://www.drugwatch.com/featured/us-drug-prices-higher-vs-world/

the maker (Allergan) of the billion-dollar drug Restastis—used to treat chronic dry eye from inflammation—who maneuvered to transfer their ownership to a Native American tribe as a tricky way to avoid U.S. laws hoping they would qualify for immunity protections as a Sovereign nation. This didn't go over so well." [6]

Finally, drug companies make a concerted effort to ensure that their negative pharma studies never see the light of day. British physician and academic Ben Goldacre's wrote about this in his book Bad Pharma. A fairly good summation of the book's first chapter "Missing Data" about Ben's findings on this:

> If the trial seems to be producing negative data it is stopped prematurely and the results are not published, or if it is producing positive data it may be stopped early so that longer-term effects are not examined. He writes that this publication bias, where negative results remain unpublished, is endemic within medicine and academia. As a consequence, he argues, doctors may have no idea what the effects are of the drugs they prescribe. [7]

So, doctors, the FDA, nor anyone else ever gets to see the entire picture when it comes to drug efficacy.

It's not just drug companies though. Medical device companies are not above sugar-coating data when trying to get coverage. At a recent MedTech Conference Tamara Syrek Jensen, director of the coverage and analysis group at the Centers for Medicare and Medicaid Services, had a simple message for device makers: Tell the truth. When a reporter stood to ask if she encountered dishonest device manufacturers "the room exploded with laughter and Jensen responded, 'So many times.'" Jensen went on to say that even if device makers themselves thought their data is not as good, there were still pathways that CMS could recommend for them to get reimbursement. "The fact that truthfully representing data is not the industry default [and] has afflicted so many is—frankly—disturbing." [8]

Another problem has to do with security. Medical IT devices are notoriously difficult to secure. When the security testing does occur, malware and vulnerabilities are still found. "Just 9 percent of device manufactures said they conducted yearly tests, with 43 percent of manufacturers saying they did not test medical devices." [9] Devices are susceptible to breaches and hacking. They must be encrypted and secured—it's imperative for the manufacturers and, obviously, the wearer.

Also, medical device fraud is a huge problem within the industry. Kickbacks are especially prevalent. Usually device firms pay doctors and providers to use their product. But there are cases where further deceptions are made.

For instance, medical device maker AngioDynamics paid hefty fines to resolve allegations that they "used misleading marketing practices and caused health care providers to submit false claims to Medicare, Medicaid, and other federal healthcare programs." [10]

This year medical technology company Stryker was fined $7.8 million by the Securities and Exchange Commission (SEC) for violating the books and records and internal accounting controls provisions for the Foreign Corrupt Practices Act (FCPA). This, after settling FCPA violation charges by the SEC in 2013 for $13.2 million. In both cases Stryker paid the settlements without admitting or denying the SEC findings. [11]

And then there is the serious accusations against Boston Scientific that were recently reported on the television news program 60 Minutes. [12] The controversy swirls around the company's surgical device implant called gynecological mesh, and, specifically, Boston Scientific's claims that the materials the device is made of is exactly what the FDA had approved, a product called Marlex. The CBS report alleges that the plastics

6 https://www.acsh.org/news/2018/09/15/pharma-and-hospital-systems-now-playing-drug-pricing-blame-game-13414
7 http://en.wikipedia.org/wiki/Bad_Pharma
8 https://medcitynews.com/2018/09/at-advameds-annual-conference-cms-official-to-industry-tell-us-the-truth/
9 https://healthitsecurity.com/news/medical-device-security-rarely-tested-in-healthcare-orgs
10 https://www.waterskraus.com/whistleblower-leads-12-5m-medical-device-fraud-settlement/
11 https://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/42820-stryker-to-pay-7-8m-to-settle-sec-foreign-corrupt-practices-act-violation-charge-5-things-to-know.html
12 https://www.cbsnews.com/news/boston-scientific-gynecological-mesh-the-medical-device-that-has-100000-women-suing/

now being using for its mesh implant are an inferior Chinese-made product, not of medical grade quality. Further, that Boston Scientific went so far as to use counterfeit Marlex bags to try to deceive the FDA. "Over five years, the FDA found that mesh supporting organs after pregnancy, had resulted in nearly 4,000 'reports of injury, death, and malfunction' and complications including 'pain, infection, urinary problems, bleeding and organ perforation.'"

The US Government

The FDA has its own problems regarding safety standards. Over the years, detractors have slammed the FDA for not speeding up their review processes, especially for those patients with rare diseases. This despite funding woes to the government agency. The FDA has recently made a concerted effort to do exactly what its critics demanded. The inevitable downside to that is the FDA may be rushing drugs out to market before risks/side-effects are determined. Nuplazid, anyone?

Many drugs granted accelerated approval by the FDA lack clear evidence of safety and effectiveness. The FDA's Accelerated Approval pathway aims to get promising investigational medicines to market quicker. But in doing so the required confirmatory studies were substantially lacking, according to studies published in JAMA. Moreover, many FDA approvals that required subsequent trials to confirm the benefits either failed outright or had early termination.

The same holds true for high-risk medical device modifications, according to another JAMA report. The article listed concerns about missing data and selection bias with regard to studies conducted for continued FDA approval of the altered devices. Study author Dr. Rita F. Redberg: "I think the public assumes that medical devices currently on the market, particularly high-risk devices, have been approved based on a high standard to show safety and effectiveness before doctors can recommend and implant them. Our findings show that this assumption is often incorrect."

While we're being lulled into a false sense of security by the FDA, US legislators are making it hard for us to actually afford the approved drugs and devices that are deemed safe and effective.

Our government (Medicare) is one of the biggest buyers of medicine. Current US law prohibits Medicare from negotiating prices directly with drug companies. Currently, the Veterans Health Administration and the Department of Defense are the only federal entities allowed to do so; they pay prices that are roughly half of those paid at retail pharmacies. Drugs are much cheaper overseas for a variety of reasons, not the least of which is that they can bargain freely.

Just as the federal government is letting us down, so are the states. "Evidence is thin that [state Medicaid contractors] improve patient care or save government money. When auditors, lawmakers and regulators bother to look, many conclude that Medicaid insurers fail to account for the dollars spent, deliver necessary care or provide access to a sufficient number of doctors. Oversight is sorely lacking and lawmakers in a number of states have raised alarms even as they continue to shell out money." [13] That is to say, ***your*** money.

States provide $300 billion/year to Medicaid insurers, who get to keep what they don't spend. The question is, are the billions in profits they're amassing the result of greater efficiencies or from denying or reducing services to their patients? Because of their lack of oversight many state representatives just don't know. And neither do we. Screwed again.

13 https://www.npr.org/sections/health-shots/2018/10/18/657862337/private-medicaid-plans-receive-billions-in-tax-dollars-with-little-oversight

Middlemen

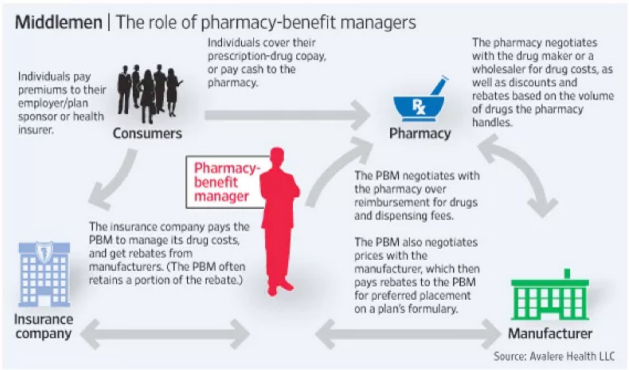
We've seen how manufacturers go to great lengths to keep drug prices secret. Prescription benefit managers (PBMs) exploit that through hidden spread pricing, i.e. the difference between the amount they reimburse pharmacies for a drug and the amount they charge their clients. "Among the generic drugs examined, pharmacies and supply chain middlemen on average added to the bill almost 32 percent in 2017, up from 24 percent in 2015." [14] How much of the spread (markup) is going to the pharmacies and how much is retained by PBMs is unclear. Finger pointing between the two continues as they fight to keep spreads a hush-hush topic.

Spreads are just one item within PBMs' veil of secrecy. Other things they'd rather not let the general public know about are:

- **Rebate Retention:** PBMs keep a portion of the drug maker's rebate for themselves as "compensation"
- **In-House Policies:** The sly maneuvering of patients to their own contracted specialty or mail-order pharmacies (despite others having better prices)
- **Clawbacks:** Taking back the difference between a patient's flat co-pay and the actual price of a drug when the co-pay is higher

Lawsuits have been filed regarding PBMs manipulating their generic drug price lists "to line its pockets at the expense of independent pharmacies."

Insurance companies are also no stranger to deceptive practices. To wit: pharmacy gag clauses. Those gag clauses forbade pharmacists from proactively telling consumers if their prescription would cost less if they paid for it out-of-pocket rather than using their insurance plan. This nefarious practice which came to light only recently was met with such revulsion that even our government took notice. Two bills, The Patient Right to Know Drug Prices Act and the Know the Lowest Price Act, were signed into law on October 10 by President Trump who expressed his support for the legislation prohibiting insurers and PBMs from using gag clauses to conceal lower prescription drug prices from patients at the pharmacy. "But there's a catch: Under the new legislation, pharmacists will not be required to tell patients about the lower cost option. If they don't, it's up to the customer to ask." [15]



Dan Fleshler, a writer and media strategist, put it best in his piece for the online site Healthline: "Currently, the pricing process is veiled by confidential contracts between PBMs and drug makers, retail pharmacies and others in the supply chain. Without bringing sunlight to that dark, murky world of backroom deals, it's impossible to assess the PBMs' precise responsibility for high drug costs and difficult to figure out how to reform the system." [16]

In short, private insurers and benefit managers reach their own deals with drug companies, and the public is left in the dark when it comes to the details of those deals.

Distributors also have skeletons in their closet. There's the case of AmerisourceBergen Corp. (ABC) who swindled not the public, but providers and the government. The drug wholesaler broke open original

14 https://www.bloomberg.com/graphics/2018-drug-spread-pricing/
15 https://khn.org/news/no-more-secrets-congress-bans-pharmacist-gag-orders-on-drug-prices/
16 https://www.healthline.com/diabetesmine/pbm-advocacy-ideas#4

manufacturers' sterile vials to create their own (unsterile) pre-filled syringes, a practice known as overfill skimming. ABC then resold them through a subsidiary that they claimed was a pharmacy to unsuspecting oncology practices. Concurrently, ABC submitted no data to the FDA ensuring the safety and efficacy of the repackaged drugs—all the while fraudulently billing Medicare, Medicaid, TRICARE, the VA, and other federal healthcare programs. ABC ended up paying fines totaling $885 million as a result of their deceptions and corruption. [17]

Lastly, representatives of the company Acclarent unlawfully "pitched the Relieva Stratus Microflow Spacer, meant to open a patient's sinus, as a steroid delivery device in order to create a new revenue stream and boost the company's prospects for an initial public offering or acquisition target." [18] The former CEO and vice president of sales of Acclarent were convicted by a federal jury in connection with distributing adulterated and misbranded medical devices related to off-label usage.

Providers

A report by The Moran Group found that hospitals charge 479% of the cost of drugs on average. [19] Again, the average person wouldn't be privy to that info since, as we know by now, actual drug prices are kept away from prying eyes.

To be fair, those ridiculously inflated drug charges is partially the fault of insurance companies demanding massive discounts from hospitals in return for sending their patients to them. And hospitals are quick to point out Big Pharma also bears responsibility, with the AHA accusing PhRMA "of pointing fingers and blaming everyone other than themselves to try to justify the dramatic increases in the prices of drugs, as they continue to make double-digit profit margins."

That quote is laughable knowing the hospitals themselves are just as cagey about revealing their prices as the rest of those on the healthcare gravy train. Hospital paymasters assign arbitrary, ridiculously inflated prices to various drugs, devices, and medical objects. Why? Because they can. We'll let Adam Conover explain hospital gouging practices [20] in this eye-opening 5-minute clip: **The Real Reason Hospitals Are So Expensive**

As mentioned in Adam's searing expose, beyond mere inflammatory charges, hospitals and insurance companies also make money from so-called "surprise" out-of-network (OON) billings to unwitting patients. For example, OON doctors and hospitals currently do not have to inform patients that they are out of network. These out-of-network billings, especially in emergency rooms where patients don't have the capacity to make decisions, can cost tens of thousands of dollars. [21] But those patients won't even know about it until they get the astronomical bills in the mail. Surprise!

Perhaps worst of all is this: People without insurance—who are plainly the ones least able to afford it—are charged hospital rates far higher than those with insurance. Not that they know that, of course.

Providers are no strangers to kickbacks either when it comes to medical devices. In a recent case neurosurgeon Sonjay Fonn and his fiancée, Deborah Seeger schemed to defraud Medicare by setting up a sham spinal-implant distributorship, DS Medical, and submitting false and fraudulent claims. That relationship violated federal law barring health-care providers from making patient referrals in exchange for any direct or indirect benefits. The couple was ordered to pay fines and damages totaling $5.49 million. [22]

17 https://www.healthleadermedia.com/amerisourcebergen-pay-625m-cancer-drug-repackaging-scheme
18 https://www.healthcaredive.com/news/recognizing-and-preventing-medical-device-fraud/430686/
19 http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf
20 Adam Ruins Everything - The Real Reason Hospitals Are So Expensive | truTV
21 https://www.motherjones.com/kevin-drum/2018/09/new-bill-will-put-an-end-to-the-out-of-network-er-scam/
22 https://www.semissourian.com/story/2554102.html

As with manufacturers, healthcare providers also shoulder responsibility for medical device security. "Exposed devices and systems could be used by cybercriminals to penetrate networks, steal data, run botnets, and install ransomware." [23] Without protocols and protection in place not only is the providers' protected health information (PHI) vulnerable, but the wearers of medical IT devices (patients) could be held hostage by terroristic cyberattacks.

Out of the Darkness

The healthcare blame game is spectacle; and so-called discounts & rebates are the sleight of hand within the show. Rather than being beguiled by misdirection and illusion you have to focus on what's real.

Among all these deceptive practices, obfuscations, and roadblocks to the truth there must be a pathway leading out of the darkness. And there is. **It's called transparency.**

Transparency in all forms within healthcare world, including specialty drug pricings, medical-surgical implants and devices costs and data, vetted medical diagnoses, approved treatments, and accurate therapeutic efficacies, is absolutely crucial to everybody—none more so than those along the healthcare payer chain.

Where there's transparency there's knowledge. **And knowledge is power.** Obtaining that knowledge and using that intelligence for your own benefit is the light switch turned on. No more fumbling around in the dark.

Advanced Medical Strategies provides the intelligence needed for payers who are struggling to predict, evaluate, and manage high dollar healthcare claims. The analytics within their Predict Suite of software solutions provides both clinical and financial clarity for an industry that desperately needs it. We're talking about full transparency regarding catastrophic diagnoses, specialty pharmaceuticals, and medical-surgical implants—available 24-7 on computer, tablet, or phone. Specifically, the Predict Suite modules include:

1. **PredictDx** – This definitive on-demand decision support solution delivers in-depth clinical information, empirical insight, and key financial analytics for the costliest medical diagnoses. Payers can more accurately predict liabilities, set reserves, assess the need for cost containment, validate standard of care treatments and eliminate the countless hours spent searching for credible financial and clinical data.
2. **PredictRx** – This comprehensive Specialty Drug directory combines the most up-to-date clinical information with drug pricing to deliver a valuable whole-picture view of specialty drugs. Each of these facets are benchmarked by the most recent and accurate data.
3. **ImplantDx** – This is the only online, fully-transparent implant cost directory in the industry. Further, by leveraging detailed clinical and financial metrics, a new basis for provider network contracting and reimbursements for implant related services is available in one click. The Bundled Procedure Module within ImplantDx provides further clarity in how costs are assigned to episodes, eliminating the medical device "black box" problem found in all other types of bundled payment groupers.

Unscrewed

Oh, and for those of you who may still be thinking about that $12,291.00 surgical screw mentioned at the top of this article, a quick peek at ImplantDx would instantly tell you how much it really cost: $1,713.05.
Welcome to the light!

23 https://healthitsecurity.com/news/medical-device-security-should-be-focus-for-healthcare-providers