



Patient Safety America Newsletter

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<http://PatientSafetyAmerica.com>

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Question: What percentage of U.S. doctors receive payments from drug and device companies each year?
a) 10% b) 20% c) 30% d) 50% e) 70%

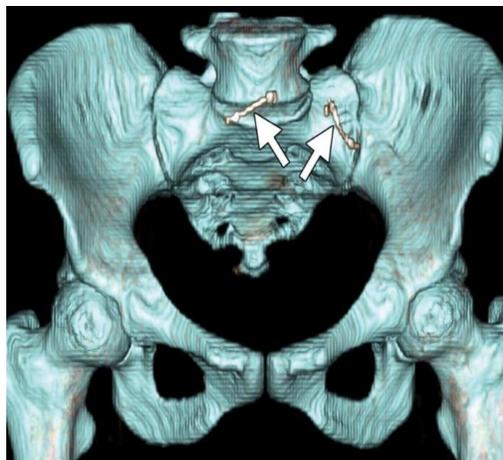
The Bleeding Edge

In the interest of full disclosure, I have worked with many of the people featured in the documentary that I discuss below. In all cases, I support their perspective that we must do a better job of protecting patients from potentially harmful devices.

Two [doctors](#) writing in the *JAMA* expressed their opinion of the documentary called *The Bleeding Edge*. Even though they had a few reservations, on balance the documentary hit on a problem in medical care that deserves more attention. They note that the core theme of the movie centers on problems with Essure, a sterilization device that is inserted in the fallopian tubes of women. It was sold to women as highly effective and minimally invasive, but problems with its safety emerged soon after its approval. Harmed women eventually found each other and through assertive advocacy, including visits to Congresswomen, Essure was taken off the market.

A secondary theme in the movie involves Stephen Tower, MD and his efforts to deal with the harm caused by disintegration of chrome-cobalt, metal-on-metal hip replacements. When these implants deteriorate, they release traces of cobalt, causing a variety of debilitating symptoms. Other less detailed attacks are made on surgical mesh implants and vena cava filters that tend to fragment.

The image shows two Essure coils (arrows). It is from <https://pubs.rsna.org/doi/full/10.1148/rg.326125501>.



Speaking for the documentary, the authors point out that harmful things happen because of poor post-marketing surveillance by the FDA and inadequacies in the 510(k) pre-market, device approval process. According to this process, a device that is substantially equivalent to one already on the market does not have to go through a rigorous approval process. This process was initially adopted to deal with a few devices, but it has become the gaping hole through which far too many devices gain approval.

Rather than throw full blame on the FDA, the writers point a finger at Congress, which has given FDA guidance that it must use the minimum amount of information necessary to demonstrate safety and effectiveness. In addition, marketing forces rather than scientific evidence too often guide what devices are implanted in patients. The writers indicate that the film fails to discuss the inappropriate uses of devices by physicians and hospitals that lead to patient harm.

The full documentary is available on Netflix. In my opinion, it discloses a system that fails to protect patients from harm, but the blame is diffused among many entities – Congress, regulatory agencies, device manufacturers, physicians, and hospitals. I am proud of the way ordinary folks have spoken up to hold this broken system accountable. Pressure must remain on if there is going to be lasting solutions. The trailer for *The Bleeding Edge* is here: <https://www.youtube.com/watch?v=slmilObZI28>. Please watch it; you'll not be disappointed.

Screening for Pancreatic Cancer

The announcement from Alex Trebek that he has stage 4, pancreatic cancer and he intends to beat it, has drawn renewed attention to this tragic cancer. Many cancers can be discovered in their early stages, but pancreatic cancer is most often apparent only when in a state of metastasis. I have a friend who has struggled for more than a year with this awful cancer. Is it possible that a screening method exists that could facilitate earlier discovery of this cancer, and if so, who should be screened?

Of the deaths caused by cancer, pancreatic cancer is third even though it an unusual type. According to an [editorial](#) the *JAMA*, pancreatic cancer kills about 46,000 American each year. Soon it is expected to be the second leading cause of cancer deaths. An expert group that does medical guidelines found no evidence that screening reduces pancreatic-cancer mortality. Part of the problem in screening is the low incidence of this cancer. However, with certain high risk groups having a lifetime incidence of 5% or more, screening may make sense. Risk factors include 2 or more family members having had the cancer or persons with new-onset diabetes, which is due to pancreatic tumor growth. The authors cite a study showing much improved survival when those with familial high risk are screened vs. no screening. There is more work to be done to fully demonstrate which populations should be screened.

Various institutes offer screening for pancreatic cancer. One is [Johns Hopkins](#). The American Cancer Society offers advice on [screening](#). The meaning of ‘new onset’ diabetes is described [here](#). It’s complicated.

Walk to Add Years

A small [team of investigators](#) asked how many ‘steps’ per day was necessary to show improved longevity in a select group of American women (average age 72). A hip-mounted monitor of steps was made available to participants who were asked to wear it for 7 continuous days (minus any water activity). Almost 17,000 women were included in the study, and they were followed for a mean of 4.3 years. The study was conducted from 2011 to 2015. Of these women, just over 500 died during follow-up. The mean steps per day were sorted into quartiles with average counts as follows: 2700, 4400, 5900, and 8400.

The investigators concluded that as few as 4400 steps per day improved mortality, which progressively improved when walking about 7500 steps per day. At this point mortality gains leveled off. Compared to a reference group of 2000 steps per day, those doing 7500 steps per day were about 60% less likely to die during the follow-up period. The investigators point out that their data are consistent with studies from other countries. One limitation is that those less able to walk may have had disabilities that affected walking and longevity. The women in the study were in general more active than average American women. For distance reference, folks walking about 3 miles per hour will do 2250 steps per mile ([steps per mile](#)).

Accelerated Approval of Cancer Drugs

In a highly troubling commentary, [three experts](#) wrote their invited comments in *JAMA Internal Medicine* on the consequences of accelerated approval of cancer drugs. In 1992 Congress authorized the FDA to approve drugs for marketing if they have been shown to improve a surrogate endpoint for cancer. For example, a surrogate endpoint might be shrinkage of tumor size by 30% or more. When a drug is approved through the accelerated pathway, the company is expected to follow that approval with studies that show it improves life expectancy and quality. The authors simply ask, “How effective has this process been in delivering safe and effective cancer drugs to patients?” The answer is ‘not very effective.’

For example, of the 93 drugs given accelerated approval, only 6% elicited complete remission of the targeted tumor(s). Moreover, tumor shrinkage is not well correlated with overall survival. Many of the drugs given accelerated approval are never properly evaluated in post-marketing trials. The FDA has actually approved drugs when they show no benefit to survival in post-marketing testing. The writers point out that the FDA shares the ‘positive’ fact that few accelerated-approval drugs have been removed from the market. The writers point out that this is not a measure of success; it is more a measure of the FDA’s reluctance to withdraw a drug when it has been proven ineffective.

The writers suggest that desperate patients often are willing to try almost anything to stop their cancer. This opens them up to false hope when a

drug without proven effectiveness and safety (extension of life and its quality) is recommended to them. This is unconscionable, they opine. They suggest that post-marketing, confirmatory endpoints should never be the same as those used in the accelerated-approval studies. Furthermore, The FDA must quickly withdraw drugs shown to be ineffective when measured by extension of life and its quality. I would ask, “Can a regulatory agency have a conscience? Where is the conscience of doctors who should know the safety and effectiveness of cancer drugs before poisoning other humans with no expectation of real gain?”

People facing deadly cancers should ask about the background of approval of drugs recommended to them. How long has it been marketed? Did it receive accelerated approval by the FDA? Have confirmatory tests been completed, and if so, what was the outcome? How much should I expect my life to be extended and at what cost in debilitating side effects? You do not want to be a guinea pig.

While we are thinking about cancer, one of the key questions is how to do payments for cancer care. An MD (Robert Steinbrook) writes his editorial comments in *JAMA Internal Medicine* about some shortcomings of the current payment system. Apparently, in 1983 Congress approved special payments to 11 hospitals that were considered excellent cancer care centers. This is called the ‘prospective-payment system (PPS)’ and it delivers hundreds of millions of dollars to these centers. But it turns out that these seem to do no better than local teaching hospitals, so why should they receive special payments from the government?

The author calls for more disclosure of the outcomes of cancer care, an end to favorable treatment of selected centers by Medicare, and ending the PPS cancer center program.

Sepsis and Government Protocols

Sepsis is a common and deadly disease. It’s definition has evolved in the past few decades, the most [recent definition](#) being ‘life-threatening organ dysfunction caused by a dysregulated host response to infection.’ Organ dysfunction may be an indicator of sepsis when the patient is also suspected of having an infection. It is very important to respond to sepsis to prevent death. That response should include antibiotics (within 3 hours) and fluid management (within 6 hours). A small team of

[investigators](#) asked whether lives were saved after the New York State Department of Health issued regulations in 2013 that were in response to [Rory’s Law](#), passed in response to the death of a 12-year-old boy to sepsis that should have been treated.

The changes in avoiding death because of the law in New York State were gleaned by comparison to changes in death rates from sepsis in other states. Once the data were adjusted for various factors (something I am always suspicious of), the authors concluded that the law was associated with a 3% reduction in death rates in New York compared to the states where no regulation was imposed. This might seem small, but based on CDC data gleaned from various sources, sepsis claims about 200,000 American lives each year. A 3% reduction in this would amount to saving about 6,000 lives per year across the country.

If you are advocating for a patient that may have sepsis, you must be highly vigilant. You do not want to be grieving a lost loved one because of poor-quality treatment of sepsis. Please read the basis of Rory’s Law linked above. It is the work of the parents of Rory Staunton.

Reduce Sodium in Food

You have no doubt heard the call to reduce sodium in your diet to reduce your risk of cardiovascular disease. Three experts wrote their [perspective](#) on barriers to accomplishing this goal. They point out that most of the sodium we consume comes from processed food and restaurant food, which contributes about 80% of dietary sodium. About 5% is from the salt we add and another 15% occurs naturally in food. The point is that individuals have a limited ability to control their sodium consumption. The National Academy of Medicine (NAM) has just reminded us that we need to start acting on this. **One cup of this soup gives almost a third of an adult daily allowance of sodium.**

Nutritional Facts		Amount/serving	%DV*	Amount/serving	%DV*
Serving Size: 1 C (245.0g)		Total Fat 4g	5%	Total Sugars	7g
Servings: about 4		Saturated Fat 1g	5%	Protein	3g
Calories 130		Cholesterol 5mg	2%	Calcium	79mg 6%
*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.		Sodium 710mg	31%	Iron	1mg 6%
		Total Carb 22g	8%	Potassium	257mg 6%
		Dietary Fiber 2g	7%	Not a significant source of trans fat, added sugars and vitamin D.	

I have an interesting memory in terms of the FDA's challenge in regulating food additives such as salt. Historically, it has been regulated under the condition called 'generally recognized as safe (GRAS).' The writers note that this cannot be done well given the evidence that high levels of salt in restaurant and processed food is in fact harmful. About a decade ago I was at a huge toxicology meeting and the FDA commissioner had just concluded her talk and asked for questions. I was the first to be called upon, and I asked her when the FDA was going to start forcefully regulating salt in food to stop the harm it causes. She struggled, muttering something about looking at doing that in the future. The FDA has done nothing.

The perspective writers declare that with the release of the recent report from the NAM, there is no longer any excuse for inaction. The hope is that food manufacturers and restaurants would voluntarily reduce sodium, but the FDA should use its power if this does not start to happen immediately.

Shared-Decision Making and Aspirin

Personally, I have struggled with whether to take aspirin to reduce the probability of a cardiovascular event – heart attack or stroke – and to reduce my risk of colorectal cancer. The weight of evidence is that the reduction in risk is slight at best. On the other hand, aspirin can cause bleeding problems, especially intracranial and gastrointestinal. Given the equivocal evidence, [three MDs](#) suggest a decision based on shared-decision making between clinician and patient with a focus on patient preferences. Note that this is only for people that have not had a heart attack or stroke. For them, the value of aspirin is clear.

What must be weighed in the shared-decision making process? Is your risk of a cardiovascular event greater than 15%? Even estimating this may prove to be a challenge because of various models and uncertainties. Are you willing to take a medication daily for many years? Do your fears of a cardiovascular event out-weigh your fears of a bleeding event? Is it going to bother you to bruise easily or bleed more from a minor cut? Yes, it's complicated.

Open Payments to Doctors by Drug and Device Companies

If you wish to determine whether your doctor or teaching hospital receives payments from drug and device companies, check this website:

<https://openpaymentsdata.cms.gov>. It is a typical, unfriendly, government website, but I was able to eventually find that there were \$3M in payments to *The Methodist Hospital* in Houston. A pair of experts [wrote about](#) their perspective on this database, which has been in operation for 5 years.



First, almost half of doctors receive some kind of compensation from the drug and device industries each year. Some prominent medical leaders have failed to report their payments. Clearly, the reach of these industries is astonishing. The writers note that this may erode patient-physician trust; however, patients seldom access this database. The authors caution that Open Payments is only a first step in transparency. We must not stop there; more transparency is needed. **See if your doctor or hospital is in the database and how much money was paid.**

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Answer to this month's question: (d). About half according to the federal database called Open Payments.

