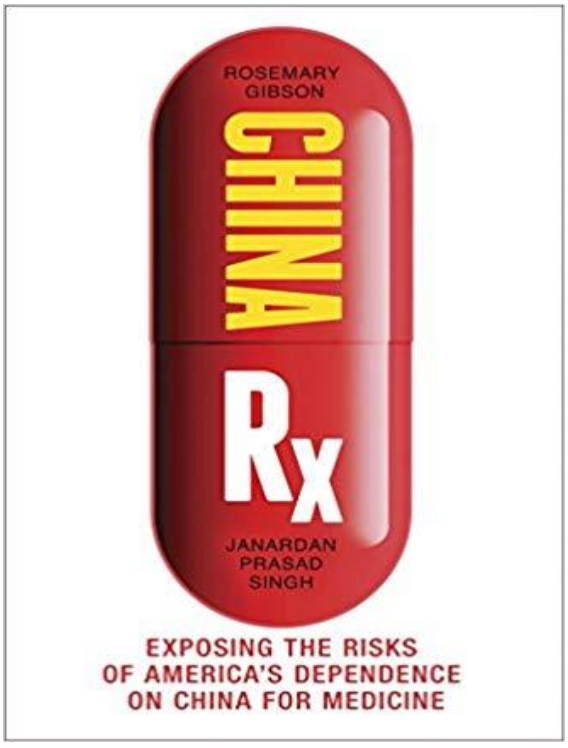
Patient Safety America Newsletter

December 2018 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: How much per person does the FDA receive each year for ensuring drug and food safety?
a) $10 b) $20 c) $30 d) $40 e) $50

Book Review: **China Rx – Exposing the Risks of America's Dependence on China for Medicine**
Rosemary Gibson and Janardan Prasad Singh

With respect to full disclosure, I consider Rosemary Gibson a friend and fellow soldier in the fight for safer medical care in the U.S. She has established herself as a first-class writer with three previous books on worrisome aspects of American healthcare. Her fourth, *China Rx*, imparts to her reader what the others have done – it tells a troubling story through many interesting perspectives and deep research into the secrets of the way illicit enterprises can victimize patients.



The book begins with the story of Bob, a victim of heparin tainted with a strange contaminant originating with the Chinese supplier of an active ingredient. The contaminant causes almost immediate, serious harm that leads Bob on a long journey whose completion is not revealed until much later in the book.

The chapters trace a mafia-like enterprise to keep secrets from patients in the interest of creating ever-cheaper ways of making drugs that may be of poor quality or contaminated. The ineptness of regulatory agencies to protect the public is reviewed, often tracing the root cause to bad rules or funding short-falls made by Congress. Chinese interests know how to influence American politicians – money and the chance to make more. The effects of China's penetration into our medication business has led many American drug manufactures to close shop, putting huge numbers of chemists out of work. Even the broadcast media seems to be complicit in the takeover of medication production by China – they have business interests in China, you know!

The other concern besides tainted medications that Ms. Gibson and Mr. Singh bring forward centers on the possibility that we Americans will not be able to get essential medications if the Chinese decide to deny them or their essential ingredients to us. There is hope if only this country's legislators will act on some of the intelligent suggestions for change.

There is one way to make that happen. Read her book, and then when the new Congress is seated, write your senators and representatives asking them what they intend to do about the impending risk of China controlling the access of Americans to safe and essential medications. Share some of the suggested solutions presented in chapter 14 – A Ten Step Plan to Bring It Home.

Although the subject of Chinese capture of medication production is troubling, the writing style in *China Rx* is so engaging and fast paced that it is an enjoyable read. It calls us to action. **5 stars.**

Drink Water to Reduce Cystitis Risk

Common knowledge suggests that drinking water reduces the risk of urinary-tract infection. In reality, this has not been objectively demonstrated in a well-done, scientific study until now. A team of investigators randomly split a group of 140 women with a history of cystitis into two groups. The control group continued their usual consumption of water, and the experimental group ingested an additional 1.5 liters (about 1 ½ quarts) of water each day for 12 months. The participants average age was 37 years, and they had had an average of 3.3 cystitis infections the previous year. During the study period, those consuming extra water averaged only 1.7 infections, whereas, the group that continued their usual habits averaged 3.2 infections. The investigators rightly conclude that water consumption was a good defense against urinary tract infections in women with a history of this illness.

The implications of this study are important. The authors point out that about 1/7th of anti-microbial prescriptions are for urinary tract infections, and this level of use may be a large contributor to the increase in antibiotic resistant infections that has many experts concerned.

Residents Reporting Diagnostic Errors

Three MDs set out to examine the support system and comfort level of physicians-in-training and attending physicians when reporting diagnostic errors to patients and other providers. They surveyed 484 physicians, mostly trainees, of which 256 responded. These physicians served in 2 university hospitals and in 4 community-based hospitals. The consensus in both groups of doctors was that there was little training on how to report diagnostic errors, there was no cohesive system for doing so, the current systems are not helpful, and there is discomfort in reporting diagnostic errors to patients.

Clearly, this needs to be fixed. One would hope that patients' voices will be heard in the way they wish to have diagnostic errors reported to them. This, in fact, would make a good subject for a survey of patients. In my opinion, the difficulty in reporting diagnostic errors is going to be directly related to how serious the outcome of that mistake has been or will be. A root-cause analysis would also be helpful after each error.

Out-of-Office Blood Pressure

The best way to determine if you need to manage your blood pressure is to make frequent measurements while engaged in life activities. One way is to employ a strapped-on monitoring device that does this every few minutes as the subject ambulates and sleeps. The other is to take morning and evening measurements, twice each time of day, with a commercially produced monitor. The authors of a brief clinical review point out the conditions under which patients should do lifestyle modifications to better control their out-of-office blood pressure, which should be below 130/80. If lifestyle modifications do not elicit a reduction to below this level, then medications may be considered.

The writers give a short list of recommended ambulatory and home blood pressure monitors. They favor the ambulatory approach, especially if the effect of medication on a patient's blood pressure must be monitored (for the purpose of titrating the dose). In-office measurements tend to be higher than ambulatory or at-home measurements, so keep this in mind if you become a candidate for medications.

Mesh Sling Removal in Women

In my journey as a patient-safety advocate, I have come across some women who are definitely unhappy with their mesh treatments. I have often wondered how frequently the initial treatments with mesh fail. Now I have an answer, thanks to research by a large team in the U.K. Investigators studied the incidence of a removal surgery performed in a group of 95,000 women that had received a first-time mesh sling. The initial mesh slings were inserted between 2006 and 2015, with a median follow up time of 5 ½ years. The chance of removal after one year was 1.4%, but after 9 years, the need for removal was 3.3%.

The authors suggest that the finding that 1 in 30 women with stress urinary incontinence who have a mesh-sling insertion will need to have it removed after 9 years may affect their decision to

have it inserted in the first place. If you wish to know more about options for treating stress urinary incontinence, please visit a Mayo Clinic website.

Actions for High Maternal Mortality

Four MDs, writing in the *New England Journal of Medicine* expressed their collective opinion on how to reduce maternal mortality in the U.S. They note that this problem has gained the attention of the mainstream news media through many portals. In fact, maternal mortality in the U.S. is worse than in other developed countries. America, we have a problem.

The Centers for Disease Control and Prevention has identified the three most common preventable problems: postpartum hemorrhage, severe hypertension, and blood clots. With attention to these risks, the writers make four suggestions. First, hospitals should focus on women with high risk for an adverse event. Second, there should be intentional staff meetings to fully assess a woman's risk factors. Third, there should be simulated obstetrical emergencies to hone immediate-response skills. Fourth, there should be improved collaboration between low-resource hospitals when a woman needs transfer to a facility with more resources.

The writers further suggest one year of further obstetrics training for primary care doctors that wish to serve rural populations. Finally, they note that hospital leaders must hold their staffs accountable and provide resources for implementation of some of these ideas.

While I realize that the writer's focus was on hospital care, it seems to me that enhanced prenatal care and postpartum follow-up might provide the greatest reduction in mortality. Hospitals don't want women showing up for the first time at their ER with extreme high blood pressure and no prenatal care. Moreover, they do not want a woman who delivered in their hospital showing up at their ER a week after discharge with life-threatening blood clots. Emerging risks must be detected at the earliest possible time to manage these before a trip to the ER becomes necessary. This also means that the mother should know how to recognize developing problems at the earliest possible time.

Informed Consent, or Lack Thereof

I'm going to continue to shine light on informed consent since this is the critical point in the relationship between clinician and patient. Patients must be ready to take control of the process if they are not being given enough information to make an informed decision or their preferences have not been elicited and respected. The debate on who should administer this responsibility continued in the letters section of the *New England Journal of Medicine.* The focus of the discussion seemed to be centered on whether a team is involved in the patient's care or there is only one primary clinician involved. If there is a team, who should be able to administer informed consent? Is there someone other than the attending physician that can do this? My recent experiences in hospitals while looking after my dad suggest that genuinely functioning teams may be rare. One of the letters called for more research about administration of informed consent and shared decision making. I would agree with that, but I would caution that patient advocates should be part of the design and execution of that research, not just clinicians.

Drug Safety in the Real World

It's no secret that the performance of a drug in a Randomized Control Trial (RCT) may be quite different than performance in the real world where medications meet patients of all sorts. A couple of MDs were invited to comment on attempts to get a better handle on real-world performance of medications. Some of the reasons for differences between a RCT and the real world may include less monitoring of real-world patients, comorbidities (illnesses different from participants in the trial), and use of other drugs in the real world that RCT subjects did not use.

One way to get a handle on the real-world performance is to analyze data from patients that have taken the drug as part of ordinary clinical care. This requires lots of data, and confounding factors abound. The authors describe studies on NSAIDs (non-steroidal anti-inflammatory drugs used for pain relief) and allopurinol, which is used to treat gout. After criticizing the studies for confounders and limitations, the authors conclude the they "soften"

the need to be so careful when prescribing these drugs to patients with comorbidities.

I am aware of protocols for drug prescribing in hospitals that could apply here. The idea is to learn from the patient as the medication is used. By this I mean that the patient knows what to look for and is appropriately scheduled for clinical monitoring (say for kidney function). Unexpected adverse events or failures to elicit the expected outcomes would immediately call for an adjustment of dose or a change to another medication. A wise patient will know what side-effects may occur with a new medication and how to report these to their clinician.

National Guideline Clearinghouse (NGC)

My readers will know that I am a proponent of medical care that follows well-vetted guidelines. These are known to improve outcomes for patients. An opinion article in the *Annals of Internal Medicine* laments the demise of the NGC due to budget cuts by the federal government. This resource provided an easily accessed and searchable database of more than 2,000 medical guidelines. It also had a feature with which to determine the quality of each guideline. In the writers' opinion, this loss will compromise the delivery of evidence-based medicine. They rightly acknowledge that guidelines cannot be applied as a "cookbook" in treating specific patients, but they will apply to the vast majority of patients.

In the last year of operation of the NGC, the cost was $1.2 million, which the authors note is small in comparison to the hundreds of millions spent on research to develop guidelines. I'd ask, "What's the point of performing research that will lead to quality guidelines if access to those guidelines is not going to be readily available." It seems to me that the priorities of your federal government are woefully misplaced when it comes to serving the public. The message to patients is to be doubly cautious in years to come when you seek quality healthcare. The tracks on which the train of evidence-based care runs have been pulled up and the metal sold to ignorance.

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Answer to question: (a) $10, actual amount is $8, China Rx, page 187