Book Reviews

Stats.Con: How We Have Been Fooled By Statistics-Based Research In Medicine, by James Penston, softcover, 319 pp, $12.99, ISBN 978-2-907313-33-2, UK, London Press, 2010.

This book is a "must-read" for all AAPS members: practitioners, researchers, administrators, and managers: an essential textbook of at least first reference and more.

It is impressive and an intellectual joy in just over 300 pages. The author is a consultant physician and gastroenterologist in a National Health Service district general hospital in the north of England, with a background in the pharmaceutical industry and clinical research. He displays a deep under-standing of the many subjects that come together in this thoroughly researched, comprehensive, intellectually stimu-lating, and—most bizarrely for a book on statistics—enjoyable text. The author explains complex subject matter absent the jargon and opaque flowery language that academics sometimes use to disguise their inability to explain their own subject. And the typeface is comfortable also.

This is not merely a book on medical statistics. It has a breadth and depth of coverage of a multiplicity of subjects that the author skillfully melds into a cohesive and cogent whole. History, philosophy, politics, corruption, and fraud, all find their place. This is not simply a case of statistical treatments of significance and confidence in numerical results—which often fail to reveal or account for the variety of methodological and other errors inherent in such studies. It is rather an elegant, deep, thorough deconstruction of current practice, revealing confusion and muddle of fundamental concepts by researcher authors of and readers of formally published medical studies.

This comprehensive treatment achieves far more than communication of its core messages: the absence of justification for the trust placed in modern epidemiological studies and large-scale randomized clinical trials, particularly where therapeutic or other claimed effects are small. The author's arguments illustrate how and why our trust in the *P*-values and confidence intervals, as measures of reliability of results, is misplaced and false.

The author's accessible style, without sacrificing rigor of treatment or accuracy of terminology, allows full rein to excite and stimulate the reader's mind. It is like a full-course gourmet meal rich in flavor. The reader comes away satisfied and wanting to return another time.

Penston argues that the grounds for causal inference in statistics-based research are lacking. Not only can we can never know whether the results of a randomized controlled trial (RCT) apply either to a particular patient or to a specified group, but the essential inference of the presence of a causal relationship, drawn from small differences in outcomes revealed by RCTs, is highly questionable. The frequentist approach to statistics used in nearly all medical research, which is based solely on the frequency with which a characteristic occurs, is unsound, and serious criticisms of it remain unanswered. The external validity of RCTs, namely the reliability of any generalization from results of an individual study to the wider population of patients, is always open to question. The size of the treatment effect in large-scale studies is very small. The true size of an effect can be, and deliberately is concealed by some researchers and others with a vested interest in the outcome of the studies. Needed close and independent examination is rarely accorded, so the dubious worth and doubtful meaning of statistical studies goes unnoticed.

The conditions for internal validity of RCTs are rarely if ever satisfied by randomization, allocation concealment, double-blind administration of treatment, the handling of withdrawals and drop-outs, and the statistical tests.

With the seeming increase in research fraud, lack of ability to confirm results is concerning. Neither the results of individual RCTs nor the statistical methods used can in general be tested independently because RCTs involve heterogeneous samples with unknown mixtures of constituents.

Penston argues that even if we were to accept the validity of causal inference in such circumstances, and to dismiss concerns about independent testing, we would still face a distasteful reality that the product of statistics-based research is of little value.

Penston shows how statistics-based research has become accepted over the past 50 years. He argues that advocates have used every means to spread a flawed methodology, and their views have infiltrated the thinking of generations of researchers, practicing physicians, and others involved in the care of patients. The implications extend beyond medicine.

While the author touches on the importance of clinical research and how statistical studies have overshadowed it, he misses answering two important questions: What is and should be the place of clinical research, evidence, and experience? And how can their rightful place in medicine be regained?

Chapter 7, "Fraud in Medical Research," might be usefully supplemented by separate treatments of the psychologies of fraud, of author biases, and reinforcements of belief in expected outcomes.

Clifford G. Miller, Esq.
Beckenham, Kent, England

Why We Get Fat—and What To Do About It, by Gary Taubes, hardback, 257pp, $24.95, ISBN 978-0-307-27270-6, New York, N.Y., Alfred A. Knopf, 2011.

> *"…The diet we have to eat to lose weight—the one restricted in fattening carbohydrates—is also the diet that will best prevent heart disease."*
> –Gary Taubes

"Why are we fat?"

"Why are our children fat?"

"What can we do about it?"

These are the questions science writer and best-selling author Gary Taubes answers in *How We Get Fat*. He states that obesity is not a disorder of overeating, or of energy balance, or of "calories in/calories out," although this dangerous idea has survived virtually unchallenged for the last 50 years. Instead, he concludes, we get fat because of the carbohydrates we eat.

Two hundred years ago we ate less than a fifth of the sugar we eat today. Fifty years ago one in every nine Americans was considered obese, whereas today it is one in three. And today more than a quarter of our adult population suffers from metabolic syndrome, which includes diabetes and obesity.

Taubes says we have been getting fat and diabetic because we have been getting the wrong advice. The vast majority of today's physicians and public health officials have a flawed "energy balance" paradigm that stipulates that the reason we get fat is as clear and incontrovertible as is the cure—that obesity is simply a problem of eating more than the body needs, and that under-eating will correct it.

A competing theory, the notion of the fattening carbohydrate, has been around for most of the last 200 years. Until the 1960s it was conventional wisdom, and it led to a string of best-selling diet books such as *Eat Fat and Grow Slim* (1958), *Calories Don't Count* (1960), *Dr. Atkins' Diet Revolution* (1972), *The Carbohydrate Addict's Diet* (1993), *Protein Power* (1996), and *Sugar Busters* (1998).

Taubes notes that since the end of World War II, the question of what makes us fat often has seemed like a religious rather than a scientific issue. By the 1960s obesity had come to be thought of as an eating disorder, so the science of fat regulation wasn't considered relevant, and this is still largely true today. In addition, health officials had become convinced that dietary fat caused heart disease.

In 1965, for example, Jean Mayer, prominent Harvard nutritionist, warned that to prescribe carbohydrate-restricted diets for the public would be "the equivalent of mass murder." By the 1970s dietary fat had become the official dietary villain; by the early 1980s Jane Brody of *The New York Times,* the most influential journalist on the subject of nutrition for the last 40 years, was telling us to eat more starches and bread as diet foods, stating, "We need to eat more carbohydrates."

In 1984 the National Heart, Lung, and Blood Institute launched its $115 million decade-long campaign to convince Americans that low-fat diets protected us against coronary heart disease. Since then we've been getting fatter instead of leaner, and the incidence of heart disease has not diminished. Even in 1995 the American Heart Association advised we could eat anything—even candy and sugar—as long as it was low in fat.

By the mid-1990s the Centers for Disease Control and Prevention and the World Health Organization declared that we were in the midst of an epidemic of obesity that they blamed on too much money and too much food. But obesity is associated with poverty, not with prosperity, as studies of the Native American Pimas of Arizona and the Sioux of South Dakota, and studies in more than a dozen other locations all over the world have shown. And under-eating doesn't correct it.

Nor does exercise correct it—despite the advice of the U.S. Department of Agriculture, the International Association for the Study of Obesity, the International Obesity Task-Force, and Jean Mayer, the most influential nutritionist in the U.S. He has been recommending exercise as a means of weight control since the 1950s. But many people exercise to work up an appetite. One researcher in 1942 calculated that one would need to climb 20 flights of stairs to use up the energy contained in one slice of bread.

In fact, the human body is perfectly able to function normally without any carbohydrates in the diet. As Taubes points out, meat contains all the amino acids, all of the essential fats, and 12 of the 13 vitamins essential for life. Only vitamin C is lacking.

It turns out that the low-carbohydrate diet we must eat to lose weight is the same diet that will best prevent disease, Taubes states. He explains that if you eat a high-carbohydrate Western diet, you expose yourself to the Western diseases. These include obesity, diabetes, heart and artery disease, hypertension and stroke, Alzheimer's and other dementias, cavities and periodontal disease, appendicitis, ulcers, diverticulitis, gallstones, hemorrhoids, varicose veins, and constipation.

Studies have shown that only a change in the regulation of the fat tissue will make us lean or obese. Fat is continually flowing in and out of the fat cells in the form of fatty acids, which the body uses for fuel. But when carbohydrate is available, insulin is secreted and the carbohydrate is used as fuel, while the fatty acids are stored in fat cells, which makes us fatter. When insulin levels fall we liberate fat from the fat tissues and burn it as fuel.

Our insulin levels are determined by the carbohydrates we eat; the more carbohydrates we eat, the more insulin we will secrete, and the more fat we will store in our fat cells. Carbohydrate drives the insulin, which drives the storage of fat. So, if you are predisposed to get fat and want to be as lean as you can be and still remain healthy, you must restrict carbohydrates and thus keep your blood sugar and insulin levels low, Taubes states.

The refined carbohydrates, such as flour and cereal grains, starchy vegetables such as potatoes, and sugars are especially liable to make us fat, increase our appetite, and make us sedentary, he argues. Even worse, these sweets are addictive—in the same way that drugs are and for much the same biochemical reasons. They trigger a response in the same "reward center" of the brain that is targeted by cocaine, alcohol, and nicotine. So the foods that make us fat (the carbohydrates) make us crave these same foods that make us fat.

Taubes has documented an alarming defect in current dietary practice. That patients must educate their physicians and public health officials about dietary science is a sad commentary on the politicization of nutritional research and much other science. Arguably, this in no small part is because of the massive increase in government funding of research that followed creation of the National Science Foundation in 1950.

Why We Get Fat should be required reading for all who want to promote better health—especially our physicians and medical students, and our public health and government officials.

Jerome C. Arnett, Jr., M.D.
Helvetia, W.V.

Stop Paying the Crooks: Solutions to End the Fraud That Threatens Your Healthcare, by James Frogue, ed., softback, 209 pp, $19.95, ISBN 978-1-933966-04-5, Washington, D.C., CHT Press, 2009.

This collection of papers by health policy wonks, many of whom would be familiar to readers of this journal, is published by the Center for Health Transformation, founded by Newt Gingrich, who wrote the foreword.

Editor James Frogue is the Center of Health Transformation's chief liaison to state policy projects. He was director of the Health and Human Services task force at the American Legislative Exchange Council for three years, and also worked with the Heritage Foundation. The book is highly praised by Sen. Tom Coburn, M.D., Rep. Michael Burgess, M.D., and Rep. Paul Ryan.

The short summary of the book is that there is an incredible amount of fraud, and the solution involves more health information technology (no surprise from Newt Gingrich's center), more enforcement, and more compliance plans.

Escalating from the earlier estimate of a 10 percent loss to fraud, bandied around for many years by the Center for Medicare and Medicaid Services, Sen. Coburn asserts that as much as 20 percent is lost to fraud in Medicare and Medicaid, while 25 to 30 percent might go to waste.

"Waste, fraud, and abuse" are often conflated, and is not clear whether Sen. Coburn is making a distinction. This book gives no basis for determining any of the percentages, or any means for distinguishing fraud from waste or abuse. The highest estimate Gingrich quotes is from James Mehmet, former chief state investigator of Medicaid fraud and abuse for New York City. He believed that 10 percent of Medicaid spending was "flat-out fraud," and another 20-30 percent was unnecessary spending, meaning that up to 40 percent of all claims were questionable.

One reason for this appalling situation is lack of data integrity, according to a very long chapter by Tom McGraw, Ingenix senior vice-president for government solutions. Yes, this is the same Ingenix that was the subject of $300 million settlement in a class-action suit brought by out-of-network providers for United HealthCare. High-quality data is key, McGraw writes. He states that linkages and cross analysis with vital records could help prevent payment of Medicaid benefits to people who have been dead for years. McGraw doesn't seem to notice any difficulties with having the government prescribe standards for interoperable health information technology for physicians, when government's own Medicaid system can't communicate with its vital records system.

Problems with data management dictate the need for the Provider Enrollment Chain and Ownership System (PECOS), according to the paper by Mark Birdwhistell, who has worked at the Medicaid program for 25 years.

It is acknowledged by Chris Kryder and Barry Johnson of the Verisk health data analytics firm that the rules are complex, time-consuming, and overhead-wasting. No one seems to have noticed that the very complexity of the rules favors enterprises that are devoted to electronic claims filing for fraudulent purposes, whereas most of the enforcement efforts are directed toward trapping individual physicians who do not manage to be in 100 percent compliance. In fact, nowhere in the book is there any acknowledgment of the abusive prosecutions of private physicians while Medicare carriers seem to get a free pass. The book seems to advocate ever more sophisticated data mining methods, rather than the rather simple one of looking at large numbers of digits to the left of the decimal point, or huge numbers of checks being written to the same entity.

To stop paying the crooks ought to be a fairly obvious solution. We should also stop paying the parasites who take advantage of the complexity of the system. But all of the authors seem to take for granted that we will continue with the same structure that they admit caused the problem in the first place: third-party payment.

AAPS has long advocated the simple expedient of outlawing the assignment of benefits. If all checks go to the beneficiaries, then there is no profit in billing for fictitious or dead beneficiaries, since the "provider" (or actually non-provider) would not be getting the money. If the beneficiary had to pay a portion of the cost, or even had to pay up-front the total cost and wait for reimbursement, then it is certain that many fewer unnecessary services would be obtained. It is puzzling why some experts who give at least lip service to the concept of consumer-directed healthcare do not see involvement of patients as essential for stopping fraud. Could this be because so many enterprises, aside from outright crooks, have a vested interested in skimming off a lot of the money that flows through the third-party payment system, without directly contributing anything to the healing of the sick?

While missing the main point on the solution to the problem, the book has a lot of references and considerable useful information. Unfortunately, the lack of an index seriously limits its usefulness as a reference. I will probably keep the book on my shelf because of information in the appendices. Appendix D is a chart of Medicaid spending per enrollee in 2006, by state. The range was from about $5,000 per enrollee in Alabama to more than $11,000 in New Jersey. There is also a list in Appendix A of state schemes for gaming the federal match. It appears that government itself may be the worst crook of all.

Jane M. Orient, M.D.
Tucson, Ariz.