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THE ROAD TO HEALTH & WELLNESS

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ELITE
PERSONAL TRAINING AND FITNESS SOLUTIONS

In every issue

The FDA Is Not Protecting Americans' Health

Introduction

This article concludes our series on the FDA and its alleged mission to protect our health. If you're short on time, please skip to the summary. However, we hope you will find this last article enlightening.

All too often, the FDA is bad medicine. Here's why:

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Making Drugs is Expensive

It should come as no shock that labs take scientific shortcuts when trying to get a treatment to market. After all, they must recoup their money. Whenever the FDA catches falsified data or unreported side effects, it is supposed to issue a warning letter to document the bad research.

Sounds good, right? The reality is that the FDA goes to extreme lengths - from bureaucratic obfuscation to outright redactions - to hide links between negligence and drugs. Thus, it's almost impossible to tell if their warning letters are doing anything to protect consumers.

SCAN ME

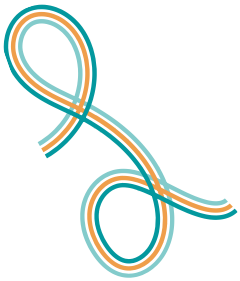
Want Some Examples?

The FDA discovered significant flaws in four of the research trials for the anti-blood clotting agent called Xarelto but never told their advisory committee. On March 25, 2019, over 25,00 plaintiffs sued the drugmakers for not warning about the bleeding risks and settled for $775 million.

About a decade ago the FDA got into trouble over a newly approved antibiotic called Ketek. Inspectors had found extensive problems (including fraud) that affected key clinical trials of the drug. Yet, the agency hid the problems from even its most trusted advisors. As David Ross, the FDA official in charge of reviewing Ketek's safety put it, "In January 2003 over reviewers' protests FDA managers hid the evidence of fraud and misconduct from the advisory committee members, who were fooled into voting for approval." Eventually, Congress stepped in and demanded information from the FDA.

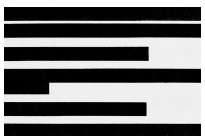
Legal Loopholes

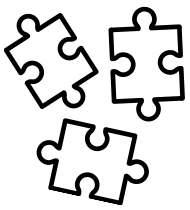
On February 23, 2020, investigative journalist Charles Seife and co-plaintiff Peter Lurie, President of the *Center for Science in the Public Interest*, won a legal victory in a lawsuit against the FDA, arguing that the agency was improperly creating a loophole in a law requiring reporting of results from clinical trials. Seife, who is also a professor of journalism at NYU, found evidence of 600 clinical trials with significant scientific and ethical lapses - lapses the FDA did their best to hide.



Connecting the Gaps

To find the connections between those lapses and the drug trials they affected, Seife had to piece together a giant puzzle of FDA paperwork. Over the course of one semester, he and his investigative reporting class issued Freedom of Information Act (FOIA) requests and combed the FDA's website to find warning letters. But the FDA removes any information in those letters that could be tied back to the drug being studied---by omitting or redacting the names of drugs, the names of clinical trials, and any information describing how the misconduct affected the outcome of the trial. Gee, how helpful.



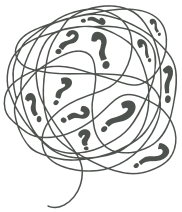


Pharmaceutical Mysteries

Seife's team had to cross-reference clues from the letters with other reports about clinical trial warnings and the occasional notification contained in a peer review. But even with a small army of grad students helping find evidence, Seife was only able to close the loop on 57 of the 600 warning letters. Whether or not the fruits of this faulty research are sitting on pharmaceutical shelves is a mystery.

These results are disconcerting, especially in the larger context of research infractions. That number has risen sharply in recent years, and the fraudulent research behind those retractions isn't limited to clinical trials. Bad science is everywhere. It's not clear whether there's more bad science than there used to be, or whether we're simply better at finding it in the internet age. Either way, it puts us at risk.

Clinical Trials



In the case of clinical trials, all this intentional fogginess makes the FDA reports useless to the public. Unless you're lucky or have the time to comb through FDA documents, you can't know whether the drugs you are taking are based on faulty research. That's scary.

Clinical trials are years-long, rigorous scientific tests that are supposed to ensure a drug does what it says it's going to do without debilitating, life-threatening side effects. The studies should be held to the highest standards possible so that your doctor can weigh the data against your patient history to make sure you get the proper treatment. If studies don't show there is a problem, then your doctor is not going to find out.

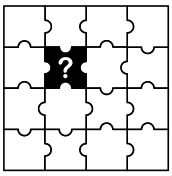
Food and Drug Administration Amendments Act

Drug makers and other sponsors of clinical trials must report their results to ClinicalTrials.gov. But even FDA overseers need oversight, in the form of scientists and researchers who provide second opinions on data from clinical trials. That's why Congress passed the Food and Drug Administration Amendments Act (FDAAA) in 2007. It's a transparency law that requires companies, universities, and government labs that sponsor clinical trials to reveal their results to patients, physicians, and independent researchers.

Cherry Picking Results

On paper, the FDAAA makes it illegal for trial sponsors to cherry-pick results, meaning publishing favorable results (like data showing safety and effectiveness) while withholding unfavorable ones (like data showing toxicity or lack of effectiveness). If independent researchers have access to all the data from all trials - favorable and unfavorable - they can double-check the work of the FDA and help keep the public informed. This isn't happening.

In practice, the mandate isn't working as well as Congress envisaged. Results from clinical trials are supposed to be posted on ClinicalTrials.gov, but quite often they aren't. More than 15 years after the FDAAA went into effect, estimates from numerous independent researchers suggest that roughly 1/3 of applicable clinical trial results (literally thousands of them) are missing!



Legal Loopholes

Part of the problem is that in 2016, the FDA's parent agency, the Department of Health and Human Services, and its sister agency, the NIH, created a loophole that exempted many clinical trials of FDA-approved products completed between 2007 and 2017 from any obligation to ever file their results with the ClinicalTrials.gov database.

In 2018, Seife and Lurie brought suit in federal court to close the loophole. Two years later, a federal judge ruled that HHS and NIH had frustrated the "unambiguous" text and intent of FDAAA and ordered the agencies to require reporting and posting of the missing data.

No Penalties

When a trial sponsor fails to post results on ClinicalTrials.gov, as required by the FDAAA, the FDA and NIH are authorized to impose penalties, including a fine of up to $10,000 a day and termination of government grant money for noncompliance.

Yet despite widespread noncompliance, these agencies have NEVER imposed a single fine, withheld a single grant, or imposed any other penalty on a noncompliant trial sponsor!

One group, the University of Oxford's Evidence Based Medicine DataLab, estimates that the FDA's lack of enforcement is so severe (and noncompliance so widespread among trial sponsors) that the FDA has forfeited billions of dollars in uncollected fines. Unbelievable.

Why Penalties Are Not Enforced

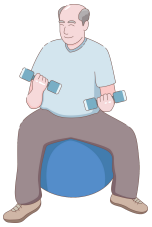
Why is the FDA ignoring this issue and the revenue it could be generating? The FDA has taken the position that enforcing the FDAAA is entirely optional. In fact, the FDA and NIH have said that even determining whether clinical trials and trial sponsors are in or out of compliance with the FDAAA is a "discretionary" task. Clearly, they don't take this mission seriously.

As a result of the unwillingness of the FDA and NIH to enforce the law, drug companies, device makers, universities, and other trial sponsors have come to expect that it is ok to withhold their results from ClinicalTrials.gov.

Without enforcement, the ClinicalTrials.gov database will remain incomplete and the purpose of the FDAAA will be unfulfilled. Without enforcement, Americans are at greater risk of wasting money on useless medical products and being injured by unsafe ones.

By removing the link between warning letters and the drug trials they impact, the FDA has hamstrung your doctor's ability to make an informed decision about your health. Talk about bad medicine!

Now let's talk about GOOD medicine. Your best bet is to stay healthy and active. Exercise regularly and eat wholesome foods. Many of our clients have been able to reduce their medications or even eliminate them! At EPT, the goal is to improve your health and wellness. In addition to personalized training, we use our health topics and newsletters to shed light on issues that impact our clients. Please reach out with your questions and concerns.



FDA Series Summary

What are the key points of our series? Here's a reminder:

1. The FDA is a derelict government organization with unethical financial arrangements [almost half of its funding comes from pharmaceutical companies].
2. The FDA focus is on drug approval not food safety.
3. FDA's drug safety approval record is beyond appalling. They recall approximately 4 drugs per day.
4. The FDA allows 3000 chemicals to be added to our food – many which are clearly harmful.
5. The FDA likens itself to a watchdog of misinformation against unsafe ineffective drugs. The reality is that they are closer to being an industry-funded lapdog.
6. If the FDA were a private company, they would be out of business rather quickly.
7. If the FDA were your employees, you would fire them for incompetent and unethical behavior.
8. The FDA has an agenda, but it is not in the public's best interest.

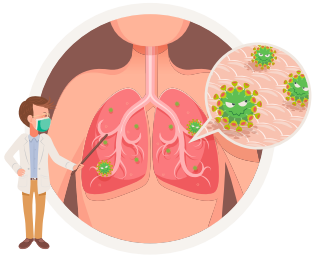
EPT has an agenda also. Our agenda is to help our clients to prevent disease and promote health by providing unbiased, well-researched and scientifically accurate information on exercise and nutrition.

Resources

Are Your Medications Safe? - Schwartzreport
FDA inspections: Fraud, fabrication, and scientific misconduct are hidden from the public and doctors. (slate.com)
FDAAA TrialsTracker: Milestones and Methodology Updates | Bennett Institute for Applied Data Science (ox.ac.uk)
FDAAA 801 and the Final Rule - ClinicalTrials.gov
FDA Can Make Us Healthier Than 'Healthy' | MedPage Today
Risky Drugs: Why The FDA Cannot Be Trusted | Edmond & Lily Safra Center for Ethics (harvard.edu)
FDA proposes using a public-health lens when considering new product approvals | Center for Science in the Public Interest (cspinet.org)
How do clinical trials work? (medicalnewstoday.com)

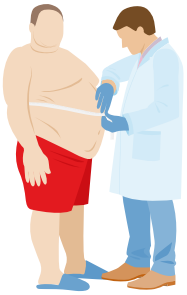
Research Shows

Here's some motivation to keep exercising this fall and winter: Exercise, even just a little, is linked to significantly lower risk of death from flu or pneumonia, according to a study published online May 16, 2023, by the British Journal of Sports Medicine. Researchers evaluated the survey responses of more than 577,000 adults who reported their health and exercise habits and were followed for nine years.



Compared with people who said they didn't meet the guidelines for weekly physical activity (150 minutes of aerobic exercise, such as brisk walking, plus two or more sessions of muscle strengthening), people who said they met both guidelines had a 48% lower risk of dying from flu or pneumonia during the study period.

Did You Know...



Seventy two percent of Americans are overweight and 48% are considered obese. Most people know that obesity increases the risk of diabetes, heart disease, and high blood pressure. But did you know that being overweight increases your chances of developing cancer, and that having an “apple” body shape due to belly fat can increase your chances of developing cancer even if you are not overweight? Although it is important to get rid of excess fat in general, belly fat is the most threatening to your health.

Food For Thought: Black Garlic

Introduction: Garlic (Allium sativum) is one of the most popular savory aromatics used in cooking. Garlic tastes great and provides tremendous anti-inflammatory and cardiovascular benefits. With the onset of fall, let's talk about something darker and more unique... black garlic!

What is it? Botanically, garlic is considered a vegetable. Black garlic is common in Korea. It is left to oxidize and ferment at low heat (140F) and high humidity (85%) for several weeks. Carbohydrates and amino acids turn dark brown due to the Maillard Reaction (pronounced My-ard after the Frenchman who discovered the chemical reaction that occurs between sugar and protein when food is heated). This reaction provides a complex taste to the surface of foods when they are roasted, seared, charred, or toasted. Heat-tolerant bacteria in garlic act to ferment the garlic during this process.

Why is it unique? Black garlic may look burnt, but it’s not. The pungent and savory flavors of garlic come from sulfur-containing compounds including allicin and alliin. In black garlic, these compounds break down to create antioxidants. Black garlic has substantially more antioxidants than raw garlic. For example, the indicative pungent and anti-bacterial compound, allicin is converted into multiple alkaloids and flavonoids in black garlic. The fermentation and aging process amplify black garlic’s benefits.

What does it taste like? Surprisingly, black garlic doesn't taste particularly garlicky. Instead, the flavor is sweet, tangy, rich, and concentrated, like molasses or dried dates, with an earthy flavor. The texture is sticky and spreadable.

Food For Thought: Black Garlic

What are the benefits? Black garlic may help protect the liver from damage and injury from short term exposure to everyday chemicals or from chronic diseases or alcohol-induced liver damage. Antioxidants in black garlic may help reduce inflammation in the brain, thus reducing cognitive decline. All forms of garlic are known to improve cardiovascular health. Black garlic may improve blood flow, help lower blood sugar levels and balance cholesterol and triglyceride levels. Caution: Those who take blood thinners should be careful when incorporating black garlic into their diet because it tends to thin the blood.

EPT Pro Tip: Want to get more garlic or black garlic in your diet but don't like the taste? Consider supplements. We provide unbiased, expert recommendations. We are not trying to sell you anything but health!

Food for Thought and Recipe contributed by Lynette Jernigan, Clinical Director of Nutrition Services and Director of Business Development at EPT.

EPT RECIPES
BLACK GARLIC

INGREDIENTS

- 6 or more garlic bulbs, whole, unpeeled
- Rice cooker or Slow cooker

DIRECTIONS

1. Remove dirt from bulbs. Remove outer paper layers without exposing the cloves. DO NOT use water or get the bulbs wet.
2. Set rice cooker or slow cooker to warm or the lowest setting available. The warm setting allows for just enough warmth and humidity to age the garlic without cooking it.
3. Place clean garlic bulbs into the cooker. Leave space in between the bulbs so they do not touch. Cover cooker with a lid.
4. Allow to sit uninterrupted until the bulbs are soft and dark brown/black in color. This may take up to 3 weeks.
5. How to know when done: The cloves will begin to shrivel and paper becomes loose. Press with your finger to check that they are very soft. Peel back a small amount of paper to check the color. It should be very dark, spongy-soft and chewy like dried dates or figs. Be sure to check the inner cloves as they may take longer.
6. Storage: Keep in an airtight container for up to 3 months.
7. Use: Squeeze out bulbs as needed for cooking or consuming.

EPT PRO TIPS

- Note: This process may produce a strong garlic odor. Please keep in a well-ventilated area.