The FDA Belongs to Big Pharma

Robert Califf’s ties to Big Pharma run deep

Scientific American reports. Califf has served as a consultant to drug companies, reports New York Times, and lead a research institute partly funded by the pharmaceutical industry.
It is hard to believe only four senators opposed the confirmation of Robert Califf, who was approved today as the next FDA commissioner. Vocal opponent Bernie Sanders condemned the vote from the campaign trail. But where was Dick Durbin? Where were all the lawmakers who say they care about industry and Wall Street profiteers making money at the expense of public health?

Califf, chancellor of clinical and translational research at Duke University until recently, received money from 23 drug companies including the giants like Johnson & Johnson, Lilly, Merck, Schering Plough and GSK according to a disclosure statement on the website of Duke Clinical Research Institute.

Not merely receiving research funds, Califf also served as a high level Pharma officer, say press reports. Medscape, the medical website, discloses that Califf “served as a director, officer, partner, employee, advisor, consultant or trustee for Genentech.” Portola Pharmaceuticals says Califf served on its board of directors until leaving for the FDA.

In disclosure information for a 2013 article in Circulation, Califf also lists financial links to Gambro, Regeneron, Gilead, AstraZeneca, Roche and other companies and equity positions in four medical companies. Gilead is the maker of the $1000-a-pill hepatitis C drug AlterNet recently wrote about. This is FDA commissioner material?

Califf has gone on record that collaboration between industry and regulators is a good thing. He told NPR, “Many of us consult with the pharmaceutical industry, which I think is a very good thing. They need ideas and then the decision about what they do is really up to the person who is funding the study.” What?

He is known for defending Vioxx which is reported to have caused at least 50,000 heart attacks and events before its withdrawal. (Merck is said to have known about Vioxx’ cardio effects but marketed the blockbuster drug anyway.)

Califf was instrumental in the Duke drug trial of the blood thinner Xarelto and a cheerleader of the drug despite medical experts’ objections to its approval and 379 subsequent deaths. Xarelto’s serious and foreseeable risks were back in the news this week.
Duke, where Califf directed clinical research, is still recovering from a major research fraud scandal that resulted in terminated grants, retracted papers and a "60 Minutes" special. It is the least appropriate place from which to choose an FDA commissioner.

Many had high hopes for the FDA when Margaret Hamburg was confirmed as commissioner in 2009 because of her public health background. But she swiftly moved to loosen conflict-of-interest rules governing those who can serve on FDA expert advisory committees and appointed Califf the FDA deputy commissioner for medical products and tobacco as she was leaving.

_The National Center for Health Research is also concerned about Califf's past ties to pharmaceutical companies and the FDA's regulation of the pharmaceutical industry. “In the last few years, FDA has lowered its standards and has been approving drugs and medical devices that are not adequately tested to make sure they are safe or effective,” Diana Zuckerman, Ph.D., President, National Center for Health Research told Naturally Savvy._

_“Too many FDA approved drugs are only marginally effective but can cause terrible harm, including drugs for hot flashes, sleeping pills, and diabetes medication,” Zuckerman explained. “The pharmaceutical companies are very happy, but consumers would not be, if they knew what was going on. That’s why the choice of FDA Commissioner is so important.”_

This is not the first time the FDA has brought in a Big Pharma cheerleader to lead the agency that regulates Big Pharma.

In 2005, a 33-year-old Wall Street insider known for recommending hot medical stocks, Scott Gottlieb, was named FDA deputy commissioner for medical and scientific affairs. When a multiple sclerosis drug trial was stopped because three people lost blood platelets and one died, Gottlieb called it "an overreaction" because the disease, not the drug, might be to blame. He rushed Chantix, Pfizer’s stop-smoking drug, varenicline, to market, which was linked to a string of 2006 suicides and the violent death of Dallas musician Carter Albrecht. Gottlieb was forced to recuse himself from planning for a possible bird flu epidemic because of his financial ties to Roche and Sanofi-Aventis and had to bow out of work related to Eli Lilly, Proctor & Gamble and five other drug companies.
Even without a Pharma-funded FDA commissioner, many dangerous drugs approved by the agency have been withdrawn due to great harm. Who remembers Vioxx, Bextra, Baycol, Trovan, Meridia, Seldane, Hismanal, Darvon, Mylotarg, Lotronex, Propulsid, Raxar or Redux?

Califf’s as head of the FDA amounts to a handover of the agency to Big Pharma.
Massive FDA crackdown coming on natural product companies: New FDA head Robert Califf unleashes sweeping nationwide surprise inspections under 2011 FSMA law

Tags: FDA crackdown, natural product companies, Robert Califf

(NaturalNews) Following the confirmation of new FDA head Robert Califf, I have been told by people in the legal field with close ties to FDA staffers that the FDA is planning to ramp up a wave of inspections and crackdowns targeting natural product companies.

This sweeping crackdown assault, I've been told, will be invoked under the Food Safety and Modernization Act (FSMA), which was aggressively pushed into law following a
series of highly suspicious outbreaks of E.coli and salmonella in food products in 2010. These outbreaks were widely publicized by the mainstream media which obeyed its propaganda marching orders from the government to whip up a frenzy of irrational fear over all fresh food. From that fear, the political establishment passed the FSMA and Obama signed it into law on January 4, 2011.

**FSMA to bankrupt small businesses by requiring pharma-level manufacturing practices**

The FSMA essentially requires all nutritional supplement, herbal formula and superfood companies to adhere to many of the same quality control procedures as multi billion-dollar pharmaceutical companies. The FDA's GMP (Good Manufacturing Practices) guidelines describe these measures and have been the law of the land since the signing of the FSMA. Yet **most small supplement and superfood companies are nowhere near GMP-compliant** due to the extraordinary costs of compliance. (Our own operation is GMP compliant, which is why I am intimately familiar with the extreme costs of compliance and the mountain of paperwork that must be produced to achieve this compliance.)

It is this non-compliance with GMP and FSMA that the FDA is now planning to use as a regulatory weapon in **nationwide, sweeping shut down of natural product companies**, I've been told.

[Click here to watch my full video commentary on this matter](https://www.youtube.com/watch?v=examplevideo), posted on YouTube. Or watch the video here (story continues below)

**And yet some of these companies legitimately deserve to be shut down...**

As the author of the new book *[Food Forensics]* -- launching July 26th in bookstores everywhere -- I fully understand that some companies in the natural products space are
irresponsibly cutting corners and totally failing to adhere to basic safety procedures in food manufacturing. So I can see a reasonable argument for taking action against the most egregious violators of food safety. But this new sweeping crack down by the FDA appears to be far more than that: It seems to be a politically motivated attempt to destroy Big Pharma's competition and further monopolize pharmaceutical profits that rake in hundreds of billions of dollars a year worldwide.

It seems no coincidence that the FDA's new head, Robert Califf, has accepted money from 23 drug companies and has already stated he thinks the FDA should be a partner of the drug industry. What better way to accomplish this than to use the FDA as a regulatory weapon to destroy Big Pharma's competition?

**Surprise inspections: The FDA Gestapo, or a legitimate public safety effort?**

Over the next several years, if my insider information is correct, the FDA plans to accelerate its surprise inspections of natural product manufacturers, shutting down as many as it can in the process.

At one extreme, this can be seen as a kind of "Gestapo" industry assault by an out of control federal regulator with a nefarious agenda of destroying the natural products industry. At the other end of this spectrum, if the FDA is very selected in its actions and only targets the very worst offenders, it could be reasonably justified as a way to improve public safety by eliminating borderline criminal product manufacturers who are likely to get somebody killed sooner or later (due to their deliberate lack of safety and testing).

It wasn't long ago that the FTC and FDA cooperated with the DOJ on the criminal prosecution of an extreme case of dietary supplement criminality, charging operators of a particularly nefarious manufacturing ring with felony crimes. Natural News supported that legal action against these alleged criminals, as they were importing toxic chemicals and pharmaceuticals from China, calling them "natural plant extracts" and dishonestly selling them in pills that targeted body builders. Those pills, the government alleges,
resulted in dozens of people suffering permanent liver damage... and possibly even a few deaths.

As the author of the Food Forensics book and the lab science director of the Natural News Forensic Food Lab, I fully support criminal prosecutions against fraudulent dietary supplement companies that are deliberately and maliciously placing customers' lives at risk in order to earn quick profits from extremely dangerous substances marketed with fraudulent claims. Yet the concern in all this is whether the FDA will limit its targeting to such egregious cases of criminal fraud, or if they will use their unbounded regulatory power as a political weapon to oppress, intimidate and ultimately decimate honest dietary supplement companies whose products compete with pharmaceutical profit interests.

With the increased interest in natural medicine products, millions of Americans are turning away from Big Pharma's toxic, overpriced drugs that don't work, instead discovering safer, more effective and far more affordable natural medicine remedies that in many cases make high-priced pharmaceuticals obsolete.
RELATED: Dr. Michael T. Murray’s *Natural Medicine Summit* begins tomorrow! Learn a wealth of knowledge about using natural medicine to prevent and even reverse serious disease.

Here at Natural News, we'll keep watching the FDA's actions with a skeptical eye, and we'll report back to you what we’re seeing and hearing from inside the industry.

**Facts about the FDA's crackdown on natural product companies**

Here are some things you need to know right now:

- The Natural News Store has already been surprise inspected at least twice by the FDA working in conjunction with Texas public health authorities. The inspectors were very professional and found zero problems in our facility. Here in Texas, we have no complaints about the professionalism of the FDA inspectors we’ve met so far. Perhaps they were happy to see that we are GMP compliant and have our own science laboratory. (We also do not push "diet pills" or scammy supplements.)

- As revealed in my book *Food Forensics*, I personally know of the existence of quite a few companies in the natural products space who are utterly failing (refusing?) to conduct even the most basic composition and safety tests of their own products. They don’t test for heavy metals, pesticides, identity tests, microbiology or anything. This is a very serious matter and it really does put the public at risk of harm. I personally am aware of a great many small companies and small operations that willfully skip all product testing because they don’t want to spend the money for such tests. Just like the recent scandal with *The Honest Company*, these operators have absolutely no idea what they’re really selling.

- The demeanor of FDA inspectors varies widely by region. I’ve heard that inspectors in certain areas of Colorado are very much Gestapo-like in their actions. The ones we’ve encountered in Texas so far have been professional yet firm. However, it is my belief
that state safety regulators should be the ones dealing with food safety on a local level, not federal regulators.

• Ironically, Natural News is likely to financially BENEFIT from the shutting down of smaller, non-compliant natural product manufacturers. In fact, the upshot of all this is that only larger product manufacturers will be able to survive the regulatory pressure. From an economics perspective, this is ultimately bad for consumers because it means fewer choices in the marketplace and less competition for innovative products.

Hurry and gain lifesaving knowledge about natural medicine while you still can

Because natural products are under assault, I encourage you to get up to speed as quickly as possible on learning about natural medicine solutions. Dr. Michael T. Murray's Natural Medicine Summit begins tomorrow! It includes compelling interviews with over a dozen of the top doctors, naturopaths, scientists and activists on the subject of natural medicine. This includes Sayer Ji who runs GreenMedInfo.com, as well as an extremely powerful interview between myself and Dr. Murray where we discuss strategic defensive eating to prevent cancer with simple foods.

Click here to register for the Natural Medicine Summit (it's free), and realize that if the FDA really gets aggressive with shutting down natural product companies, you are going to have fewer and fewer choices in acquiring natural medicine.

ACTION recommendations for acquiring safe natural medicine and dietary supplements

Recommendation #1) GROW your own medicinal herbs. This is the No. 1 way to acquire them. My Food Rising Mini-Farm Grow Box has just been released in version 2.0, now available at SupplySource.com. It grows medicinal herbs with no electricity, no weeding and no routine watering. It's the easiest way to grow your own medicine, period!
Recommendation #2) **BUY** superfoods and natural medicine products only from companies that are GMP compliant and who routinely engage in scientific testing of their products for heavy metals, microbiology, pesticides and more. The [Natural News Store](http://www.naturalnews.com/053219_Robert_Cal...) is, to my knowledge, the only online retailer in the world that owns our own high-end analytical laboratory and routinely conducts such tests of our products.

Recommendation #3) **SUPPORT** the natural product industry by purchasing honest products from honest operators. Despite the failures of a few of the bad apples in the industry, by and large the natural products industry is *extremely honest and highly beneficial to public health*. There are hundreds of quality companies offering honest, safe products that truly help prevent disease and enhance health.

**Sources for this article include:**


[http://foodforensics.com](http://foodforensics.com)


[http://labs.naturalnews.com](http://labs.naturalnews.com)


