Jonathan W. Emord

DID YOU KNOW?

That contrary to the First Amendment, the Food and Drug Administration censors all health claims that associate a nutrient with a disease? Truth is no defense. Unless pre-approved or permitted by the FDA, all treatment claims are forbidden; all prevention claims are forbidden. Period.

The FDA opposes approval or permission in all but a very small number of cases. By doing this, the FDA dishonors and violates the Constitution. The FDA has become a renegade agency that presumes itself above the higher law, and worse, presumes it free of constitutional limits to exercise its power.

What if we were suddenly freed from this agency's stranglehold on the truth?

What if FDA censorship was to suddenly end and the intent of our Founding Fathers was instantaneously restored?

What if the FDA was denied of any power whatsoever over speech and press? What would this America look like?

Imagine something for a moment.

Tonight, before you go to bed, imagine you pray for an end to FDA censorship.

Imagine further that when the sun rises tomorrow a miracle has occurred and all those who censored speech at the FDA were to have that same censorship fall upon them. Imagine they couldn't conceive of how to issue a single order to silence any speaker in the United States. Imagine what the marketplace would look like.

Let's be clear. I don't mean to suggest the Department of Justice should be disarmed of the power to prosecute.

If it were proven by clear and convincing evidence that people were engaged in deceptive practices or the sale of harmful products, they would be prosecuted. Fraud would still be illegal. However, the vast majority of those now silenced, who dreamed of the day when they could tell the truth, would have the right to speak the truth. If that freedom were restored their dream of telling the truth about the healthful benefits of their products would be fulfilled.

Free Speech Could Lead to Better Health Information

Follow me as we navigate through that day when a bold new market was created and the aggressive hand of FDA censorship was stayed. Our first stop would be at our regular gas station.

While the car filled with gas, we entered the quick mart connected to the station.

There next to candy bars and other sugary items, we would find an array of healthy, energy enhancing products.

Products containing B vitamins, amino acids and other nutrients that increase energy naturally and listing the beneficial results that have been scientifically proven. Imagine having a truthful choice.

With the car ready to go, we next head to the grocery store. As we walk in, we're surprised to find a large display area bearing a banner that reads, Disease Fighting Foods in Our Store." In the display section, you'd find brochures of various kinds identifying specific products that enhance your health and the specific nutrients they contain. The brochures clearly explain what the products do for those who are healthy and for those who suffer from specific ailments.

The booth would also contain an interactive computer that was also accessible from your personal computer at home. It would invite you to type in your age, weight, height; ask basic questions about the status of your health; ask you to list the prescription drugs, vitamins and supplements you're currently taking. Then it would ask you to select from a menu of keys to help guide your purchases at the grocery store. All this before you put one item in your shopping cart.

Imagine having a personalized list that identified the best dietary supplements for you and your family and the best foods to buy. It would also alert you to the foods you should avoid, especially those known to contain GMO's, have high sugar content, hydrogenated oils or other disease causing agents.

Imagine having before your very eyes, a personalized guide to the disease fighting foods available in that very store. Imagine having the latest information based on peer-reviewed scientific studies on the effects of nutrients in supplements and foods. You would hold in your hands a guide to the most nutritious foods and supplements to include in your family's daily diet.

As you shopped the aisles, you could follow the personalized recommendations with the confidence that you are making the best choices for the health of you and your family. Conversely, if you chose to not follow the recommendations, in part or whole, you would know in advance the potential health consequences of making poor choices and be responsible for them.

Armed with the knowledge to maximize healthful choices, you would become part of an empowered consumer movement that would profoundly transform the American diet and alter the marketplace.

Food manufacturers responding to significant changes in consumer demand would alter the composition of prepared meals, cereals and snacks and replace harmful sugars and artificial ingredients with natural health enhancing sugar substitutes such as Stevia. Good fats, such as coconut oils, would replace bad fats, such as hydrogenated oils. Flax seeds high in alpha linolenic acid would become more common in processed foods than less healthy seeds. Fish containing high omega-3 levels, such as tuna, would become more readily distinguishable from others containing lower omega-3 levels.

The superior benefits of vegan and vegetarian diets over diets dependent upon meat would become more apparent to consumers. Consumption of organic raw fruits and vegetables would increase over pesticide ridden inorganic substitutes. And the larger consumption of the organic products would lower the prices because of the demand. Consumers will come to understand that maintenance of their health through healthful living is a personal responsibility, just like proper parenting.

What we eat does largely influence our health and lifestyles. We would become, as never before, masters of our own biological destinies. Reliant on self-help through daily preventive maintenance, we would witness a dramatic reduction in the incidence of food-related diseases such as diabetes, cancer, and cardiovascular disease. Those already afflicted with those diseases would know, at the point of sale, how best to channel their purchases to reduce or eliminate their afflictions.

Medicine Would Change Fundamentally

Physicians would see fewer patients suffering from disease brought on by poor eating habits and lifestyles. Rather than rely on drug interventions to mask symptoms of disease, physicians would come to maximize reliance on alternatives to the use of caustic drugs in the long-term care of patients. They would embrace patients as partners in the evolution of their wellness, rather than view them as broken machines in need of immediate, albeit temporary, fixes.

If FDA censorship of nutrient-disease information were to end, our nation would witness an extraordinary use in average states of health; an extraordinary rise in productivity and quality of life far into the senior years; an increase in the gross domestic product; a great lessening of dependence on welfare; and a vast improvement in the quality, safety, and reliability of food stuffs and supplements. Far from causing greater fraud and abuse in the market, a truly free market would enable consumers to identify, through informed consumer choice, the very best products that enhanced a vibrant, healthy lifestyle.

There's no greater enemy to fraud than a fully informed consumer. Consequently, fraud, too, would become less commonplace. Perhaps greatest of all, were cur prayers answered and censorship lifted, we would once again become sovereign citizens, not servile victims of a paternalistic stale that thinks it knows better than we do what is in our own best interest. lmagine that.

AHN v Sebelius by Jonathan W. Ernord

Since Chief Justice John Marshall's decision in Marbury v. Madison (1803), the federal courts have exercised judicial review over laws created by the federal courts and agencies, ensuring a constitutional check on abuse of power. When the federal courts' constitutional orders are followed, the rule of law prevails. When they are not, the rule of law is replaced with the rule of designing politicians and, at least for a moment in time, our Constitution is suspended in its effect. We experience a constitutional crisis.

The Food and Drug Administration (FDA) has been ordered by the federal courts on seven occasions to humble itself before the First Amendment to the United States Constitution and to refrain from exercising its power to censor nutrient-disease claims that are supported by credible scientific evidence. Like a snake held by the neck, the agency writhes this way and that, endeavoring to lose itself from the Constitution's hold. On several occasions it has given the federal courts the slip, proceeding back to that very position that it was forbidden to occupy.

In the 1999 landmark decision Pearson v. Shalala the United States Court of Appeals for the D.C. Circuit ordered the FDA to permit nutrient-disease claims to reach the public even if those claims were not approved by the agency, stating that the less speech restrictive alternative of a claim qualification was the FDA's only constitutional resort.

Since that time, the FDA has repeatedly refused to abide by that final and binding decision. In their stubborn refusals, the FDA Commissioners from David Kessler to Margaret Hamburg have proven that they regard themselves above the law. Their decision to violate, rather than uphold, this critical constitutional mandate in defense of the people's liberties, reveals the FDA is governed by the dictates of those appointed to run the agency, who arrogantly presume the law to be no barrier to their ambitions. The recent decision of ANH v. Sebelius is an excellent case in point.

Following a series of losses to plaintiff s on First Amendment grounds between 1999 and 2001 the FDA, in response to a health claim petition filed for selenium and cancer risk reduction, surprised spectators when it authorized the following two claims, thus avoiding another fight:

1 Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

2 Selenium may produce anti carcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anti-carcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.

Like the Elephant that Never Forgets

The agency's political appointees have long disliked the qualified health claims regime imposed on it by the Court of Appeals in Pearson v. Shalala.

The agency let five years pass before it announced in the Federal Register an interest in reevaluating the selenium claims, signaling its interest in censoring them once again. On June 19, 2009, petitioners rose to the occasion and filed new health claim petitions not only for the original two claims but also for eight more selenium-site specific cancer risk reduction claims. Contrary to statements made by the FDA in its Federal Register notice of 2007, the evidence associating Selenium with reduction in the risk of cancer had grown substantially since the original two claims were allowed by the agency. In the scientific community, there is little doubt that selenium produces anti-carcinogenic effects in the body The FDA responded to the petition by denying seven of the claims and allowing modified versions of three others. Of the claims allowed by the FDA, each was rewritten by the agency and each was required to carry a contradictory disclaimer that denied the existence of supporting evidence. They also re-imposed requirements for qualified claims that exceeded the Pearson v. Shalala standard. Under Pearson, the FDA was required to allow claims it did not approve if those claims were backed by credible scientific evidence. It was forbidden from condemning claims that were backed by science even when it viewed the science as inconclusive. Rather, its constitutional resort was to let the people choose how much faith to place in a relationship when informed that the science was not conclusive.

The Presence of Inconclusive Science is the Norm

Very few relationships in science are ever accepted as conclusive. Indeed, most life-affecting decisions we make or are made for us every day involve choices based on inconclusive science. In short, we bet every day that everything from a seat belt to a splint for a broken bone will perform in a certain way that is not proven to a conclusive degree. While the scientific Evidence may be inconclusive, it may be credible, suggesting an association. To deny consumers access to the evidence of the association, on the basis that the evidence is inconclusive, deprives them of vital information on which they could make a purchase (or place a bet). Thus, knowing that omega-fatty acids are associated with a reduction in the risk of sudden death heart attack can guide e consumer in choosing to consume those substances on the bet or hope that in an individual case omega- 3s may fend off sudden death, albeit the scientific evidence of that association is not conclusive.

Conclusive scientific evidence is very hard to come by and arguably never arrives. So, were we to limit the universe of information that the government declares conclusive, we would be information poor; denied basic associational data between foods and elements of foods; and further, disease risk reduction that could adversely affect our quest to prevent and overcome the ravages of disease. In its zeal to ensure protection for a monopoly on therapeutic claims for drugs, the FDA has repeatedly censored nutrient-disease information about foods and supplements. The future of FDA Commissioners arid political appointees lies not in the supplement business but in the drug business, either as agents for drug companies, as lobbyists in support of drug company interests, or as academics whose chairs are funded by drug companies- Is it any wonder, then,

that FDA Commissioners so readily endorse FDA Anatomy Of A Victory Over The FDA censorship of nutrient-disease information?

On August 4, 2009, the selenium-cancer risk reduction petitioners Alliance for Natural Health, Durk Pearson and Sandy Shaw, and the Coalition to End FDA and FTC Censorship, sued the FDA for its decision to censor the selenium claims.

On May 27, 2010, Judge Ellen Segal Huvelle of the United States District Court for the District of Columbia issued a landmark decision condemning the FDA's censorship.

The FDA'S Contempt for the Rule of Law

In the FDA's argument to Judge Huvelle, the agency took the brazen position that she should overturn the Pearson decision. The position revealed the FDA'S contempt for the rule of law.

In our precedent based system of law, it is beyond the power of a lower federal court to overturn a decision of a higher federal court. Thus, by asking Judge Huvelle to overrule the Pearson decision, the FDA was asking Judge Huvelle to violate the governing law and presume herself possessed of a power beyond the limits of the law. Moreover, the FDA demanded that the Court defer to the agency's judgment on whether its censorship violated the First Amendment, arguing That Judge Huvelle should consider the deference ordinarily accorded the FDA for actions taken under the Administrative Procedure Act applicable to a direct First Amendment challenge. This, too, would only be possible it the governing law were overthrown, because the standards that govern constitutional challenges call for the Courts, not the federal agencies, to make the penultimate decision as to whether an agency action violates the Constitution

Judge Huvelle rejected the FDA's attempts at undoing the governing law."The Court concludes that ft is obligated 10 conduct an independent review of the record and must do so without reliance on the Agency's determinations [of] constitutional questions," she wrote. She went on to apply Pearson v. Shalala to the claims, concluding each one under review unconstitutionally suppressed.

She concluded "that the FDA's position fails under Pearson I." She reviewed the FDA's evaluation of the scientific evidence, pointing out that the FDA had "disregarded" studies submitted by the Plaintiffs that were in fact supportive of the Plaintiffs' claims, had excluded other studies from its review that were supportive of the claims, and had even denied claims that the government in argument admitted were "literally true" (the and-carcinogenic effects and overall selenium cancer risk reduction claims).

In examining the claims the FDA superficially "allowed," the Court agreed with the plaintiffs that "the FDA's proposed claims" were "at odds with the Supreme Court's mandate that there be a reasonable fit' between the government's goal and the restrictions it imposes on commercial speech." She stated further, "the agency has not drafted a 'precise disclaimer' designed to qualify plaintiffs' claim. . . It has replaced plaintiffs' claim entirely. And the Agency's 1qualification' effectively negates any relationship [between selenium and the disease]." She found that the language of the disclaimers contradicted the claims and defeated their very purpose. She also found the language inaccurate. She held the qualifications unconstitutional under the First Amendment: "[T]he FDA'S replacement of plaintiffs' claim with different and contradictory language is inconsistent with the spirit, if not the letter, of Pearson."

After this victory over FDA censorship, the agency recoiled, as it had once before on the heels of First Amendment decisions against It when it initially allowed two selenium claims. This time, following

negotiations with the Plaintiffs, It allowed use of the following claims on selenium-containing dietary supplements:

Prostate Cancer Claim "Selenium may reduce the risk of prostate cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer."

Colon and Rectal Cancer Claim

"Selenium may reduce the risk of colon cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium nay reduce the risk of colon cancer."

And

"Selenium may reduce the risk of colorectal cancer. Scientific evidence concerning this claim is inconclusive.

Based on its review, FDA does not agree that selenium may reduce the risk of colorectal cancer."

And

Selenium may reduce the risk of colon and rectal cancer. Scientific evidence concerning this claim is inconclusive.

Based on its review, FDA does not agree that selenium may reduce the risk of colon and rectal Cancer."

Certain Cancers Claim and Anti-carcinogenic Effects Claim

Selenium may reduce the risk of bladder, colon, prostate, rectal, and thyroid cancers. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of these cancers."

The Battle to End FDA Censorship is Far From Over

It will likely not be over until the FDA is forced by statute to relinquish the power of prior restraint over commercial speech. In the Health Freedom Act, Congressman Ron Paul would remove that power from the FDA. He would thus restore the First Amendment to its rightful supremacy. The First Amendment was intended to deny the federal government any power whatsoever over speech and press. It was, at its core, a denial of the power of prior restraint in this government. Until the First Amendment is restored to its position of primacy by action to remove FDA jurisdiction over commercial speech, we can expect the FDA to abuse its power.

Serving the interests of its favored regulate, the pharmaceutical industry.

Jonathan W. Emord is a constitutional and administrative lawyer in Washington, D.C. He has defeated the FDA in federal court a remarkable seven times. Congressman Ron Paul calls Jonathan a hero of the health freedom revolution." He is the author of four critically acclaimed books, Freedom, Technology, and the First Amendment (1991); The Ultimate Price (2008); The Rise of Tyranny (2009); and Global Censorship of Health Information (2010).His books are available for purchase through Amazon.com. He is the host of Health Law arid Politics on the Talk Star Radio Network. He is the 2008 recipient of the Cancer Control Society's Humanitarian of the Year award.