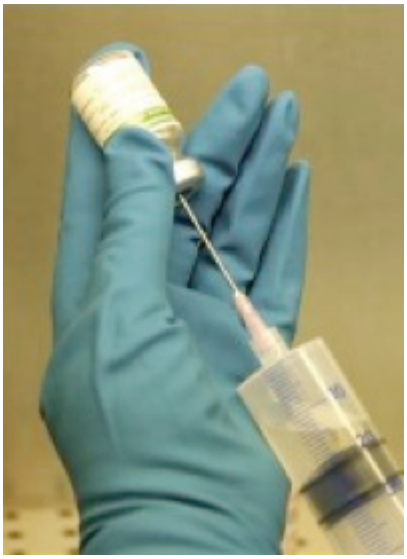
Written by **Michael Tennant** on October 18, 2010

FDA Cracks Down on Unapproved Chelation Products



The Food and Drug Administration, in its role as enforcer of politically-acceptable medical practice, has just "sent warning letters to several companies notifying them that the substances they sell without a prescription for a procedure known as 'chelation' are 'unapproved drugs and devices,' which makes them illegal," according to a report in the Washington Post. Chelation therapy is a well-established treatment for patients who have been exposed to high levels of heavy metals such as lead; there are even FDA-approved prescription-only products for administering the treatment. However, as the Post points out, "the companies that received the warning letters sell products without a prescription, often as 'dietary supplements,' and describe multiple health benefits, none of which have been proven, the agency said."

There lies the nub of the matter: Those selling these products, often on the Internet, have not bowed and scraped before the potentates at the FDA; and undoubtedly, the products they are hawking cannot be patented by the big pharmaceutical companies whose interests the FDA lives to protect. Therefore, they must be crushed lest Americans come to believe they have the right to determine for themselves which medical treatments they wish to employ.

The FDA's Deborah Autor told the *Post*, "These products are dangerously misleading because they are targeted to patients with serious conditions and limited treatment options. The FDA must take a firm stand against companies who prey on the vulnerability of patients seeking hope and relief." To an FDA bureaucrat, taking away one of a "limited" number of treatment options for "patients with serious conditions" is somehow for the best. It just wouldn't do to let the patient choose which treatment to undergo.

Speaking of companies who "prey on the vulnerability of patients seeking hope and relief," how about all those drug companies whose products have been approved by the FDA only to end up causing serious harm? The *Post* mentions that FDA officials say that unapproved chelation "substances may cause serious health complications, including dehydration and kidney failure, and possibly be deadly." Yet, to take just one example of harm from approved drugs, the FDA approved the diabetes medicine Avandia and then helped its manufacturer cover up a study that showed the drug posed serious heart attack risks.

"The agency," says the paper, "is aware of the death of one autistic child who underwent the procedure," though it is careful not to assert that the procedure was the cause of the child's death.

Criminal charges filed against the doctor who administered the treatment were dropped. Dr. Joseph Mercola, a nationally recognized expert on alternative medicine, wrote concerning the incident:

> Chelation therapy — as well as some other alternative treatments — is not entirely without risk. However, you see far more lawsuits and headlines in major media when something goes wrong as a result of an alternative therapy than when a more conventional treatment takes a life, which, by the way, happens hundreds, if not thousands of times a day.

Many conventional physicians who are critical of chelation routinely use drugs like Risperdal and Clonidine when treating autism, despite the fact that the safety and effectiveness of these drugs in children have never been established, and death is a known side-effect of such drugs.

However, deaths and serious adverse effects from "standard drug treatments" do not attract similar media attention or outrage.

It's ironic in a way, when you consider the fact that a mere 15 percent of all conventional medical treatments have been proven safe and effective in practice. The other 85 percent is pure guesswork and trial and error, and yet this is what the masses cling to as the gospel of safety.

Charles Lee of the FDA's division of new drugs and labeling compliance admitted to the *Post* that "we don't have evidence of a lot of adverse effects [from chelation products], but [that] does not mean there are not health problems associated with them" — shades of former Defense Secretary Donald Rumsfeld's comment with regard to Saddam Hussein's mysteriously missing weapons of mass destruction: "The absence of evidence is not evidence of absence."

Even if the FDA had real evidence that chelation products are dangerous, so what? The federal government has no constitutional authority to prohibit people from using products that Washington doesn't like. Moreover, the very notion that there exists some group of "experts" who, given the authority to determine which treatments shall be made available, can make healthcare risk-free for everyone, is absurd. Every treatment, including those approved by the FDA, contains an element of risk. Why shouldn't the patient who is assuming the risk be permitted to make his own decisions as to which treatments he will accept? As economist David Henderson put it, "The FDA may have some expertise when it comes to drug safety and efficacy, but on the only issue that matters — your trade-offs between various risks — you are the expert, and the FDA's scientists are rank amateurs."

A word to the FDA: Leave the chelation-product merchants alone. Let patients, doctors, and researchers determine which products are safe and effective for which symptoms and share their discoveries with others — the same process that has been used for decades to discover alternative ("off-label") uses for FDA-approved drugs. In other words, let medical freedom ring.