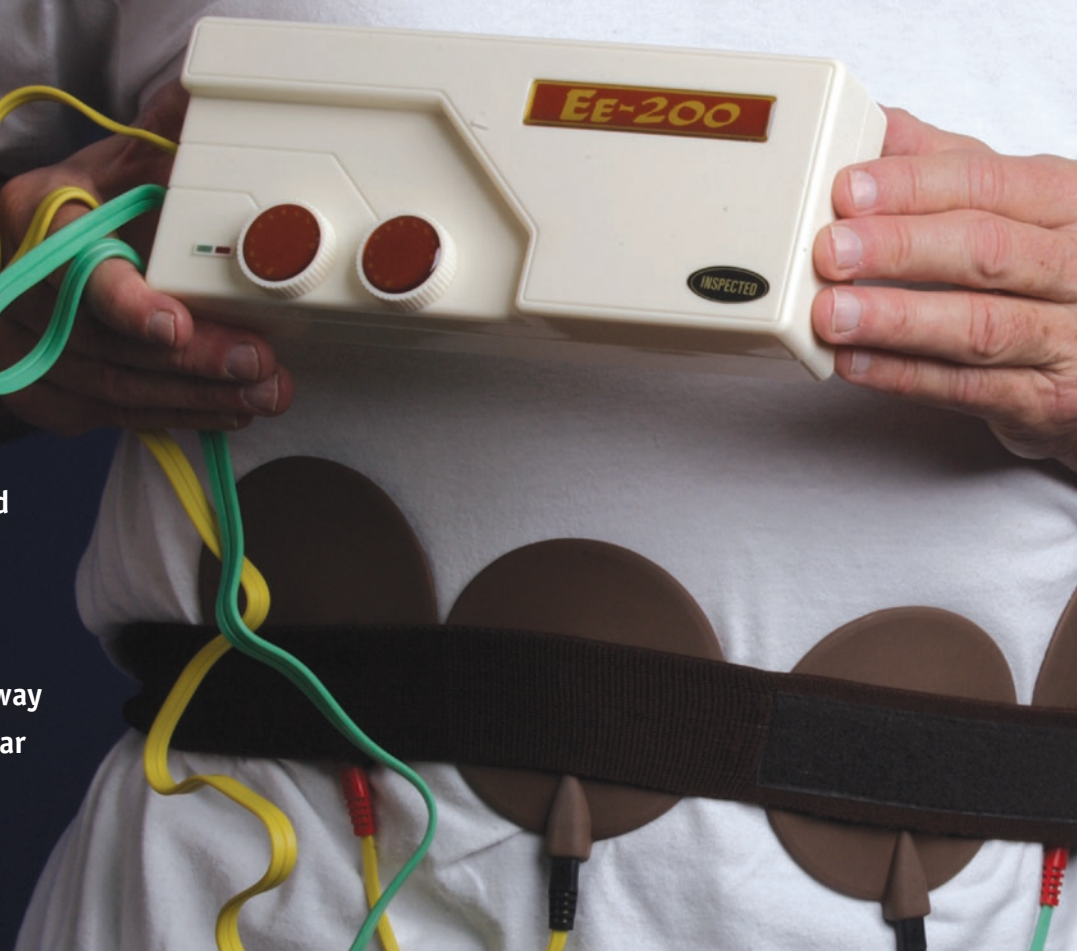


# FDA 101: Health Fraud Awareness

This unapproved medical device, "The Fitness Machine," was promoted as a way to get a muscular workout.



Black Star / John Troha for FDA

**H**ealth fraud is the deceptive sale or advertising of products that claim to be effective against medical conditions or otherwise beneficial to health, but which have not been proven safe and effective for those purposes.

In addition to wasting billions of consumers' dollars each year, health scams can lead patients to delay proper treatment and cause serious—and even fatal—injuries.

Since the 1990s, peddlers of fraudulent "health" products have used the Internet as a primary tool to hawk their wares. This has kept the U.S. Food and Drug Administration (FDA) and other agencies busier than ever in protecting the public from health fraud.

Since June 2008, FDA has warned consumers not to use bogus cancer-treatment products marketed online by 28 U.S. companies. These products include tablets, teas, tonics, salves, and creams sold under more than 180 different brand names.

And since December 2008, FDA has warned about more than 70 weight loss products containing unapproved pharmaceutical ingredients and chemicals not listed on the labels. Some of these ingredients

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present serious health risks when taken in dosages recommended on the product label.

### **Common Types of Health Fraud**

**Cancer fraud:** Among the many long-running cancer scams is the Hoxsey Cancer Treatment, an herbal regimen that has no proven benefit. Another scam involves products called black salves. These are offered with the false promise of drawing cancer out from the skin, but they are potentially corrosive to tissues.

Cancer requires individualized treatment by a specialized physician. No single device, remedy, or treatment can treat all types of cancer.

Patients looking to try an experimental cancer treatment should enroll in a legitimate clinical study. For more information, visit the National Cancer Institute Clinical Trials Web site [www.cancer.gov/CLINICALTRIALS](http://www.cancer.gov/CLINICALTRIALS).

**HIV/AIDS fraud:** There are legitimate treatments that can help people with the human immunodeficiency virus (HIV). While early treatment of HIV can delay progression to AIDS, there is currently no cure for the disease.

Relying on unproven products and treatments can be dangerous and cause delays in seeking legitimate medical treatments that have been proven in clinical trials to improve quality of life.

Safe, reliable testing to determine whether you have HIV can be done by a medical professional.

To date, there is one FDA-approved testing system that allows individuals to test themselves at home. It is an HIV collection system that tests only for HIV-1, which is the cause of the majority of the world's HIV infections.

The test, sold either as The Home Access HIV-1 Test System or The Home Access Express HIV-1 Test Sys-

tem, allows blood samples to be sent to a laboratory for testing with an FDA approved HIV-1 test.

**Arthritis fraud:** The U.S. Federal Trade Commission says consumers spend about \$2 billion annually on unproven arthritis remedies that are not backed by adequate science.

For current, accurate information on arthritis treatments and alternative therapies, visit the Arthritis Foundation Web site at [www.arthritis.org](http://www.arthritis.org).

**Fraudulent "diagnostic" tests:** Doctors often use in vitro diagnostic (IVD) tests—in tandem with a physical examination and a medical history—to get a picture of a patient's overall health.

These tests involve blood, urine, or other specimen samples taken from the body. They help diagnose or measure many conditions, including pregnancy, hepatitis, fertility, HIV, cholesterol, and blood sugar.

It's rare that the use of only one of these tests can provide a meaningful diagnosis. You can buy IVD tests in stores, through the mail, or online. Many of these tests are regulated by FDA and sold legally. However, many others are marketed illegally and do not meet FDA's regulatory requirements. These tests may not work or may be harmful.

To find out whether FDA has cleared or approved an IVD test for a particular purpose, call FDA at (888) 463-6332, or your local FDA district office [www.fda.gov/Safety/ReportProblem/ConsumerComplaintCoordinators/default.htm](http://www.fda.gov/Safety/ReportProblem/ConsumerComplaintCoordinators/default.htm).

**Bogus dietary supplements:** The array of dietary supplements—including vitamins and minerals, amino acids, enzymes, herbs, animal extracts and others—has grown tre-

mendously.

Although the benefits of some of these have been documented, the advantages of others are unproven. For example, claims that a supplement allows you to eat all you want and lose weight effortlessly are false.

Claims to treat diseases cause products to be considered drugs. Firms wanting to make such claims legally must follow FDA's premarket New Drug Approval process to show that the products are safe and effective.

**Weight loss fraud:** Since 2003, FDA has worked with national and international partners to take hundreds of compliance actions against companies pushing bogus and misleading weight loss schemes.

FDA has recently enhanced efforts to stop sales and importation of—and to warn consumers about—weight loss products that contain dangerous prescription drug ingredients that are not listed on the label.

### **Sexual enhancement product fraud:**

FDA has warned consumers about numerous illegal drugs promoted and sold online for treating erectile dysfunction and for enhancing sexual performance.

Although they are marketed as "dietary supplements," these products are really illegal drugs that contain potentially harmful ingredients that are not listed on the label.

**Diabetes fraud:** FDA has taken numerous compliance actions against sales of fraudulent diabetes "treatments" promoted with bogus claims such as

- "drop your blood sugar 50 points in 30 days"
- "eliminate insulin resistance"
- "prevent the development of type 2 diabetes"

## *It's ultimately up to the buyer to beware of potential health fraud.*

- “reduce or eliminate the need for diabetes drugs or insulin”

**Influenza (flu) scams:** Federal agencies have come across contaminated, counterfeit, and subpotent influenza products.

FDA, with U.S. Customs and Border Protection, has intercepted products claimed to be generic versions of the influenza drug Tamiflu, but which actually contained vitamin C and other substances not shown to be effective in treating or preventing influenza.

### **Don't Be a Victim**

It's ultimately up to the buyer to beware of potential health fraud. Know of the potential for health fraud and learn about the common techniques and gimmicks that fraudulent marketers use to gain your attention and trust.

For instance, testimonials from people who say they have used the product may sound convincing, but these can easily be made up. These “testimonials” are not a substitute for scientific proof.

Also, never diagnose or treat yourself with questionable products. Always check with your health care professional before using new medical products.

Be wary of these red flags:

- claims that a product is a quick, effective cure-all or a diagnostic tool for a wide variety of ailments
- suggestions that a product can treat or cure diseases
- promotions using words such as “scientific breakthrough,” “miraculous cure,” “secret ingredient,” and “ancient remedy”
- text with impressive-sounding terms such as: “hunger stimulation point” and “thermogenesis” for a weight loss product


- undocumented case histories by consumers or doctors claiming amazing results
- limited availability and advance payment requirements
- promises of no-risk, money-back guarantees
- promises of an “easy” fix
- claims that the product is “natural” or “non-toxic” (which doesn't necessarily mean safe)

Don't be fooled by professional-looking Web sites. Avoid Web sites that fail to list the company's name, physical address, phone number, or other contact information. For more tips for online buying, visit [www.fda.gov/buyonlineguide/](http://www.fda.gov/buyonlineguide/)

### **Report Problems**

If you find a person or company that you think is illegally selling human drugs, animal drugs, medical devices, biological products, foods, dietary supplements, or cosmetics, report it to FDA.

To report problems with FDA-regulated products, visit [www.fda.gov/opacom/backgrounders/complain.html](http://www.fda.gov/opacom/backgrounders/complain.html)

To report unlawful sales of medical products on the Internet, visit [www.fda.gov/oc/buyonline/buyonlineform.htm](http://www.fda.gov/oc/buyonline/buyonlineform.htm). 

This article appears on FDA's Consumer Updates page ([www.fda.gov/ForConsumers/ConsumerUpdates/default.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm)), which features the latest on all FDA-regulated products.

### **For More Information**

FDA, FTC Warn Public of Fraudulent 2009 H1N1 Influenza Products  
[www.fda.gov/bbs/topics/NEWS/2009/NEW02007.html](http://www.fda.gov/bbs/topics/NEWS/2009/NEW02007.html)

H1N1 Flu: FDA Responds Quickly to Protect the Public's Health  
[www.fda.gov/consumer/updates/H1N1virus051209.html](http://www.fda.gov/consumer/updates/H1N1virus051209.html)

Beware of Online Cancer Fraud  
[www.fda.gov/consumer/updates/cancerfraud061708.html](http://www.fda.gov/consumer/updates/cancerfraud061708.html)

The Possible Dangers of Buying Medicines Over the Internet  
[www.fda.gov/consumer/features/drugsonline0707.html](http://www.fda.gov/consumer/features/drugsonline0707.html)

Fake Cancer Cures  
[www.fda.gov/cder/news/fakecancerures.htm](http://www.fda.gov/cder/news/fakecancerures.htm)

Buying Diagnostic Tests From the Internet: Buyer Beware!  
[www.fda.gov/cdrh/consumer/buyer beware.html](http://www.fda.gov/cdrh/consumer/buyer beware.html)

Approved HIV Tests  
[www.fda.gov/cber/products/testkits.htm](http://www.fda.gov/cber/products/testkits.htm)

Tips for Preventing Medicaid Fraud and Abuse  
[www.cms.hhs.gov/FraudAbuseforConsumers/05\\_Tips\\_doc.asp#TopOfPage](http://www.cms.hhs.gov/FraudAbuseforConsumers/05_Tips_doc.asp#TopOfPage)

Reporting Unlawful Sales of Medical Products on the Internet  
[www.fda.gov/Safety/ReportaProblem/ucm059315.htm](http://www.fda.gov/Safety/ReportaProblem/ucm059315.htm)

Reporting Unlawful Sales of Medical Products on the Internet  
[www.accessdata.fda.gov/scripts/email/oc/buyonline/buyonlineform.cfm](http://www.accessdata.fda.gov/scripts/email/oc/buyonline/buyonlineform.cfm)

Reporte de ventas ilegales de productos medicos a traves del internet  
[www.accessdata.fda.gov/scripts/email/oc/buyonline/sp\\_buyonlineform.cfm](http://www.accessdata.fda.gov/scripts/email/oc/buyonline/sp_buyonlineform.cfm)