WHAT YOU SHOULD DO:

1) Call the U.S. Capital Switchboard (800-972-3524) to be connected to your senators and representatives. Ask for their fax numbers. Send a copy of the enclosed letters to your two senators and representative. Address them as follows: The Honorable (your senator's name), United States Senate, Washington DC, 20510; The Honorable (your congressman's name), United States House of Representatives, Washington, DC 20510.

2) Send a copy of this letter to President Clinton at the White House:

The White House
1600 Pennsylvania Avenue
Washington, DC 20500

White House comments line: **202-456-1111**
White House fax line: **202-395-1232**
White House email address: president@whitehouse.gov

3) File the enclosed Freedom of Information Act request by faxing and/or mailing it to:

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

FAX: **301-443-1726**
FAX: **301-443-6591**
FAX: **301-443-6463**
FAX: **301-594-0413**

If you do not get a response within 14 business days, call the following phone numbers or send a fax to the following numbers to demand a response. The Freedom of Information Act mandates that the government must respond within 10 days to all requests:

Commissioner's Office: **301-827-2410, FAX 301-443-6591**
Office of Consumer Affairs: **800-532-4440**
Associate Commissioner for Consumer Affairs: **301-443-5006**
Deputy Associate Commissioner: **301-443-5006**
Office of Regulatory Affairs: **301-827-3101, FAX 301-443-6591**

4) Photocopy, mail, e-mail or fax these letters to everyone you know who believes that Americans should continue to have free speech and health freedom. You can download form letters by accessing The Life Extension Foundation website at **www.lef.org**. Just click on the **Freedom In Healthcare** button. Keep up with current political developments by checking into the Foundation's website at **www.lef.org.** ■

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" FDA - Health Fraud - Codex "

A BRIEF SUMMARY

1) On **August 18, 1997**, the FDA issued an internal memo stating: **"Health fraud has been defined by the agency as the promotion of unproven medical products."**

According to this definition, the FDA can censor or shut down every alternative healthcare publication and radio and TV show in the United States, as well as many mainstream publications and shows.

2) In early **September 1997**, the FDA convinced British authorities to raid companies shipping European medications to Americans for personal use. Millions of dollars worth of medicines were seized, and the British authorities have threatened to shut down every company that ships European medications to Americans.

The FDA's use of the police in other countries to deny Americans access to alternative therapies may soon spread to Germany, where pharmaceutical ginkgo, DHEA and melatonin are produced. If the FDA puts pressure on the Japanese government, shipments of coenzyme Q10, green tea extract and a host of other Asian herbal extracts could be halted.

3) In Britain, the government is moving to turn supplements that contain more than 10 mg of vitamin B6 into prescription "drugs." The French are debating about how much vitamin C can be contained in a tablet before it becomes a "drug." In Norway it is already illegal to sell more than 200 mg of vitamin C without a prescription. In Germany, selenium is considered a toxin and is difficult to obtain anywhere in the country. The Canadians have banned chromium, melatonin, DHEA and a host of high-potency nutrient formulas.

A bill has passed in the Senate by a 98 to 2 margin that would harmonize regulations in the United States to reflect those of countries where dietary supplements have all but been banned.

If this bill becomes law, many dietary supplements will be removed from the market place. This bill is now in the House of Representatives. We urge every American who cherishes his or her health freedom to protest vigorously!

TURN THIS PAGE TO FIND OUT WHAT YOU CAN DO TO STOP THE FDA'S UNCONSTITUTIONAL ACTIONS

Date:_____

The Honorable _____, Washington, DC:

Dear Member of Congress:

On my behalf, I request that you seek an explanation from the FDA regarding the following two issues:

Issue One: I have discovered that the U.S. Food and Drug Administration is failing to enforce the laws that protect the safety of our blood supply. The result is that hepatitis C is now afflicting people at epidemic levels in the United States. I know the FDA is inspecting blood banks more frequently than in the past because of political pressure. My concern is that the FDA is constantly finding contaminated blood, but is not seeking civil or criminal remedies against the responsible parties in order to deter the banks from contaminating blood in the future.

I have further discovered that the FDA has chosen to use its resources to deny hepatitis C victims a medication that could save their lives. The FDA has spent large amounts of taxpayer dollars to send their agents to Europe to stop American hepatitis C patients from obtaining a drug called **ribavirin** that is being used successfully in Europe to fight this disease. I want to know why the FDA is denying hepatitis C patients ribavirin, a safe and effective medication that has been proven (in controlled clinical studies) to work.

I look forward to receiving a copy of your letter to Acting FDA Commissioner Friedman along with a response that deals with these life and death issues. I will not accept a bureaucratic boiler-plate explanation from the FDA for these immoral, and possibly illegal, acts.

Issue Two: On Aug. 18, 1997, in an internal memo, the FDA defined "health fraud" as "the promotion of unproved medical products." The FDA also reversed its policy allowing Americans to import safe and effective unapproved medications from other countries for their own personal use. The FDA now says that anyone in the United States who promotes unapproved drugs in any way is committing "health fraud."

These new policies threaten my life by denying me access to information about non-toxic alternative therapies to FDA-approved drugs. I am concerned that the FDA will use this Orwellian definition of "health fraud" to arbitrarily shut down any vitamin company, alternative medicine doctor, or health food store the agency wishes to target. The FDA's new policy also means that newspaper, magazine and book publishers, as well as radio and TV producers, risk committing "health fraud" every time they inform the public about the latest scientific findings about the value of vitamins, minerals, amino acids, herbs, or any other product shown to help prevent or treat diseases. It gives the FDA the right to prosecute criminally anyone in the United States who is involved in alternative medicine.

Please write to Acting Commissioner Friedman at the FDA to seek the following:

1) A new definition of "health fraud" that meets Constitutional standards.

2) A letter from the FDA that formally recognizes my right to import the medicine(s) and dietary supplements of my choice for my own personal use.

3) Action by the FDA to force British authorities to release ribavirin and other lifesaving medicines they've seized, so that Americans may once again obtain these medicines. Thank you.

Constituent _____

Address:_____

City_____ ST_____ ZIP_____

Date:_____

The Honorable _____, Washington, DC:

Dear Member of Congress:

I request that you sponsor and support an amendment to the House companion bill to S.830, the FDA Reform Bill, which was recently passed in the Senate. This amendment is needed to address a clause in the bill that calls for the harmonization of U.S. Food and Drug law with the European Union (EU).

Unchanged, this law gives the FDA a legal mandate to regulate dietary supplements as "drugs," which will rob Americans of free access to vitamins, minerals, amino acids, herbs and other nutrients, and will lead to much higher prices for these supplements.

Access to dietary supplements is highly restricted in Europe. In Norway, for example, it is illegal to buy vitamin C in doses higher than 200 mg without a doctor's prescription. In the United Kingdom, there is a move to make it illegal to purchase doses of vitamin B6 higher than 10 mg without a doctor's prescription. Thus, it is clearly not in the best interests of Americans for our food and drug laws to be "harmonized" with the laws in Europe.

You may have heard that the harmonization language in S.830 pertains only to medical devices, but that is not the case. It applies to the entire food, drug and cosmetic act, which includes dietary supplements. If you have any doubts about this, please read section 202 of the bill, which is reproduced below:

"Sense of the Committee Regarding Mutual Recognition Agreements and Global Harmonization Efforts: (1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move towards the regulation of drugs, biological products, devices, foods, [which includes dietary supplements] food additives, and color additives, and the regulation of good manufacturing practices between the European Union and the United States. . . ."

The FDA reform bill is on a very fast track through Congress. The Senate ignored citizens' efforts to remove the above harmonization clause, so we are now appealing to members of the House to keep Americans from losing their right to free access to dietary supplements. As of Oct. 1, 1997, the House companion bill to S.830 did not yet have a number. HR 1411 is one of three bills currently being combined to form the House companion bill to S.830. What follows is the language I would like you to sponsor, as an amendment to the bill.

"(C) The secretary shall participate in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the secretary determines that such harmonization will continue consumer protections consistent with the purposes of this Act. The Secretary shall report to the Committee on Commerce of the House of Representatives of the Senate at least 120 [instead of 60] days before executing any bilateral or multilateral agreements, and all harmonization agreements entered into must be approved by Congress following an open public hearing, in which citizens are given adequate notice and time to comment on all aspects of the bill."

This amendment would provide Americans with badly needed oversight that doesn't exist in the bill at present. If this change is <u>not</u> made, I will lobby to veto the bill and will encourage others to do so as well.

Constituent _____

Address:_____

City_____ ST_____ ZIP_____

Date:_____

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: FREEDOM OF INFORMATION ACT REQUEST

FAX: 301-443-1726
FAX: 301-443-6591
FAX: 301-443-6463
FAX: 301-594-0413

Dear Sirs:

Pursuant to the Freedom of Information Act, 5 U.S.C. 522, I hereby request copies of all documents and drafts thereof (including non-identical copies) that pertain to:

1) The names, agency addresses, and telephone numbers of all FDA officials and employees who work in the District Office nearest to my home address that are in charge of deciding whether or not I can import a medication from another country for my own personal use. My home address can be found at the end of this FOIA request.

2) The names, agency addresses, and telephone numbers of all the FDA officials and employees who work in the District Office nearest to my home who are responsible for regulating blood banks and making sure that blood products are safe.

3) The names, positions, and annual salaries of every FDA official involved in the issuance and/or execution of search and seizure notices in early September 1997 by the British Medicines Control Agency against three companies that ship medications to Americans for personal use.

4) The amount of taxpayer dollars the FDA has spent (including all expenses such as airfare to Europe, hotel rooms, meals, long-distance phone calls etc.) regarding the investigation of companies that ship unapproved drugs to American citizens for personal use.

As used in this request, references to all items listed in this request include all investigations and the findings that have occurred as a result of these investigations and agency actions that have been taken regarding these matters. The term "document" is used in the broadest sense and includes, but is not limited to, any writing and record of every type or description, whether printed or recorded (mechanically or electronically), or reproduced by hand, including without limitation, correspondence, memoranda, telegrams, reports, or notes of meetings, conferences, phone logs, telephone calls, or other conversations, phonograph, tape or other telephone calls, or other conversations, tape or other recordings, data compilations, forecasts, brochures, and pamphlets.

If you conclude that any of the requested documents are exempt from disclosure under the Freedom of Information Act, I request that you exercise your discretion to disclose these records nevertheless.

If you conclude that any of the requested documents contain both exempt and non-exempt material and you decide not to disclose the exempt material, I request that all non-exempt material be disclosed and that the deletion of exempt material be plainly and conspicuously indicated.

If you determine that any documents or parts of documents are exempt and you decide not to release such documents or parts of documents, I request that you specify which exemption(s) contained in 5 U.S.C. 552 (b) you believe covers each document or part of a document that you decide not to release.

If you determine that any requested documents for which the agency does not have identical copies are not in the possession of the agency, I request that you identify all federal agencies or other entities believed to possess such documents and the specific documents or categories of documents believed to be in possession of each federal agency or other entity.

I request that any notification of this determination be provided within ten days of the submission of this request even if you find it necessary to extend the basic ten-day response time in order to locate and copy requested documents that are in possession of the Department.

Send your response within ten days to:

Name _____

Address _____

City _____ ST _____ ZIP _____

Signed: _____

A History Of Political Persecution

Ribavirin is manufactured in the United States by ICN Pharmaceuticals. The FDA has a long-standing political vendetta against ICN because it has issued press releases on the benefits of ribavirin for a wide range of viral diseases. The FDA defines any promotion of any drug they have not yet approved (such as ribavirin) as "healt4h fraud."

ICN Pharmaceuticals has been under continuous legal attacks by the FDA since 1988. Under intense political pressure, the FDA finally did approve ribavirin for a rare viral infection that affects infants. When ICN Pharmaceuticals tried to "promote" the use of ribavirin to doctors as a potential therapy for viral infections in adults, the FDA convened a grand jury and threatened to indict the corporation on criminal charges of "promoting an approved drug for an unapproved use." ICN pleaded guilty, paid a fine, and agreed never again to promote ribavirin for uses not approved by the FDA.

In private conversations, government officials have said that the FDA will never approve ribavirin for adults because ICN has tried to go "behind the back" of the agency to encourage Americans to use ribavirin for "unapproved uses."

Why This Is A Medical Emergency!

Hepatitis C is a highly dangerous virus that damages liver cells by interacting with iron to cause massive free radical damage. If an active hepatitis C infection is not controlled, permanent liver damage occurs, often necessitating a liver transplant. The damage done to the liver cells' DNA creates mutations that make hepatitis C patients especially vulnerable to primary hepatocellular carcinoma. This form of liver cancer is usually considered to be a death sentence because there is no proven treatment for it.

The benefits of ribavirin in suppressing or eradicating hepatitis C infection are well documented in the scientific literature. As a result, American hepatitis C patients have turned to offshore suppliers of ribavirin in order to try to save their lives.

The Life Extension Foundation is dedicated to making the most advanced medical therapies in the world available to the sick and dying. The Foundation will taking extraordinary steps to ensure that people do not die because government bureaucracies choose to deny patients, such as hepatitis C victims, access to ribavirin and other potentially lifesaving medications.

The FDA must be forced to tell the British authorities to release ribavirin and the other lifesaving medications they've seized or American citizens will die!

Please send the enclosed protest letters to your congressional representatives and to The White House. In order to save the lives of hepatitis victims who need ribavirin, send the enclosed Freedom of Information Act request to the FDA to help identify the criminal agents within the FDA who are depriving Americans of a lifesaving drug. ■

You can keep up to date about this political crisis by checking The Foundation's website at www.lef.org.

Letting Hepatitis C Patients Die

There is not enough room in this mailing package to detail the illegal acts the FDA has initiated recently. The full story will be revealed in an upcoming issue of Life Extension Magazine and on our web site (www.lef.org), but the example below should make the blood boil of anyone capable of human compassion.

Hepatitis C is a chronic viral disease that has already infected four million Americans. The hepatitis C virus causes severe liver cirrhosis that often necessitates a liver transplant. About 20% of hepatitis C victims develop primary liver cancer that is virtually incurable. Many of those infected with hepatitis C suffer debilitating flu-like symptoms that prevent them from leading a normal life.

The FDA's failure to regulate the blood-banking industry is a major cause of the hepatitis C epidemic. Instead of taking enforcement action against the blood banks, however, the FDA has become part of an international conspiracy to deprive hepatitis C victims of a drug that could save their lives. The FDA is squandering taxpayer dollars by sending their agents to Europe to initiate raids against companies offering a drug that is highly effective against the hepatitis C virus.

Everyone knows the FDA is too slow in approving new lifesaving drugs. What makes this case unique is that many hepatitis C victims contracted their disease because of the FDA's corruption. Now the FDA is trying to deny hepatitis C victims access to a proven drug that could eradicate the virus from their bodies.

The Hepatitis C Drug

Since 1986, **The Life Extension Foundation** has recommended that Americans with hepatitis C import **ribavirin** for their own personal use. The Foundation previously published data from many studies showing that **the combination of ribavirin and the FDA-approved drug alpha interferon increases the effectiveness of alpha interferon alone by 2 to 3 fold in treating hepatitis C liver infections.**

In the Sept. 23, 1997, issue of ***The Wall Street Journal***, there was a report on a blockbuster new study showing that **ribavirin (plus alpha interferon) is ten times more effective in treating hepatitis C than alpha interferon alone!**

Ribavirin is a broad-spectrum anti-viral that is sold over-the-counter in many countries. Its only serious side effect is anemia in people who take high doses over long periods of time. This new study showed that **the addition of ribavirin to alpha interferon causes a 10-fold increase in the destruction of detectable hepatitis C virus in patients who had no previous success with interferon alone!**

In early September of this year, the FDA persuaded British authorities to **seize ribavirin that was being shipped to American hepatitis C victims.** The FDA shut down three companies in England that had been shipping ribavirin (and other lifesaving drugs) to Americans under the FDA's personal importation policy, and has threatened to have them all shut down within weeks.