The FDA’s Dirty Little War

How the government is scaring the hell out of alternative health advocates

August 1, 1994 By Bob Lederer

For David Merriweather, an HIV positive man in Seattle, it was a living nightmare. The date was May 6, 1992, and he was watching television coverage of an armed raid of his doctor’s office, the doctor who helped him develop a nutritional treatment program on which Merriweather was thriving. Local police and federal agents of the Food and Drug Administration (FDA) had stormed the clinic of Harvard-educated Dr. Jonathan Wright, held the receptionist and staff at gun point, occupied the premises for 11 hours and confiscated vitamins, medical equipment, computers and the medical records of Merriweather and more than 100 other patients.

The FDA had earlier sworn to a federal judge that it needed a search warrant to prove that Wright was using imported injectable B vitamins (approved by the German government but not by the U.S.) and an unapproved, non-invasive allergy screening machine. At a press conference, however, FDA District Director Roger Lowell ignored these charges, holding up a vial of moldy liquid magnesium, saying “This stuff could kill you.” Only later did the FDA admit that it had found the vial during months spent digging through the clinic’s outdoor dumpster. Local police apologized for their role in the raid, saying the FDA had claimed it would be a “drug bust.”

No charges would ever be filed against Wright, nor would his vitamins or patient records be returned, yet a grand jury probe continued for two years, subjecting staff and patients to interrogation. Wright called the raid “simple retaliation” for a lawsuit he had filed earlier challenging the FDA’s seizure of his nontoxic supplies of the amino acid L-tryptophan. David Merriweather became one of Wright’s first patients to speak out publicly against the FDA’s tactics, and he organized friends to attend a large demonstration protesting the raid.

On the other side of the country, in New York City, long-term AIDS survivor Fred Bingham (profiled in *POZ*, No. 1) could hardly believe his eyes. Here was a June 1993 report by a top-level FDA Dietary Supplements Task Force proposing the incredible: that some vitamins and minerals be restricted to low dosages, with high potentcy tablets to be banned except by prescription; that all amino acids -- such as N-acetyl-cysteine (NAC) and glutathione -- be removed from sale until their manufacturers could navigate the endless drug approval process; and that many herbal remedies be deemed “food additives” too unsafe to sell unless elaborate toxicology tests and other safety studies were performed. All this was proposed in the name of vague “safety concerns.” Yet these were precisely the types of virtually nontoxic nutritional products that -- together with some

experimental drugs -- had helped Bingham since 1989 to gain 50 pounds, reduce his foot neuropathy (tingling pain) and rebuild his immune system from the point of collapse to a stable 900 T-cells. They were also the product categories sold at discount by the nonprofit AIDS buyers club called Direct AIDS Alternative Information Resources (DAAIR), which Bingham had started.

Furious, Bingham demanded to testify before a congressional hearing. The next month, he told the assembled representatives and a national television audience, “Unhindered access to high, yet safe, doses of antioxidants, amino acids, herbs and other natural products is an absolute necessity of life if I and other people with HIV are to continue to thrive. We will not allow their removal under any guise without substantial and well-organized national protest.”

Perhaps more than any other FDA action, the raid against Wright and the Task Force report have sparked a renewal of the perennial “vitamin wars” raging around the country and in Congress. On the front lines of those wars are people with HIV and AIDS. While the question of how to protect consumers of nutritional supplements from profit-hungry companies is surely complex, one thing is simple: Consumers are increasingly demanding the right to informed freedom of choice.

As grapevine wisdom is fortified by more scientific studies, HIV positive people are adding supplements to their treatment packages in ever greater numbers, particularly as an inexpensive, low-toxicity form of early intervention. Last year two studies of several hundred people each at the University of California and Johns Hopkins University found that substantial nutrient supplementation reduced progression to full-blown AIDS by 30 percent and 40 percent respectively. Smaller studies showed promising results for particular antioxidants such as beta carotene, glutathione and NAC. Last November, the National Institutes of Health (NIH) convened its first Conference on HIV and Oxidative Stress, which pointed to a promising role for antioxidants in HIV therapy. No wonder buyer’s clubs such as Fred Bingham’s DAAIR are growing by leaps and bounds.

But the FDA argues that serious dangers lurk in the supplements marketplace. As consumer demand mounts for less toxic alternatives to risky and ineffective drugs, supplements have become a highly competitive $4.1 billion-a-year industry. Like any other industry, some manufacturers and retailers peddle products with either exaggerated claims or false labeling on potency or purity.

So, how are consumers to be assured of high quality, honestly marketed nutritional products? The industry claims its self-regulation does the job, but few outside its ranks agree. It is left, then, to the FDA to enforce the Food, Drug and Cosmetics Act against unsafe and falsely promoted foods and health products. Yet some AIDS activists charge that the FDA has actually pursued an antisupplement campaign of intimidation disguised as consumer protection, while avoiding cracking down on genuine offenders, particularly in the area of false potency labeling.

Says Michael Onstott, the HIV positive chair of ACT UP/San Francisco’s Alternative Treatment Committee, “Again and again, the FDA uses Gestapo tactics to raid companies, stores and clinics -- all in the name of providing protection from fraudulent or dangerous products. But what’s often

happening is the armed enforcement of one side of a pseudo-scientific argument. The FDA hurls the accusation 'unproven' at a health claim as if it meant 'disproven,' ignoring objective research behind it. Or agency bureaucrats reject ample evidence of product usefulness or safety and brand opponents as snake oil sellers or menaces to public health."

For example, FDA officials have often seized various rare vegetable oils, claiming that they constitute "dangerous unapproved food additives." This refers to a 1958 law requiring safety approvals for chemicals of unknown risk added to foods as colorants, preservatives or flavor enhancers. The courts have repeatedly ruled these FDA seizures illegal. In one case, *U.S. v. Traco*, the FDA has claimed that black currant oil was unsafe; yet, in court, its top scientist admitted that no experts knew of any such dangers. A federal appeals court judge held that "the only justification for this Alice in Wonderland approach is to allow the FDA to make an end run around the statutory scheme." In another food additive case involving supplements, an appeals court found the FDA's arguments "nonsensical" and said the agency "undermines legislative intent."

As Exhibit A in its case for tougher safety standards, the FDA often points to the 38 deaths and 1,500 illnesses in 1989 traced to one batch of a Japanese company's L-tryptophan. But Steven Fowkes of Direct Action for Treatment Access, a San Francisco based advocacy group for people with life-threatening illnesses, argues, "Even the Centers for Disease Control and Prevention (CDC) found that the problem was a contaminant introduced into that company's product because of a reduced purification process. It was simple corporate carelessness, yet the FDA persists in claiming that uncontaminated tryptophan may also be dangerous." Meanwhile the agency still allows tryptophan's inclusion in infant formulas and intravenous feeding solutions. Adds Fowkes, "Although this double standard doesn't make any medical sense, it might make economic sense for a pharmaceutical-friendly FDA to ban this generic sleep inducer and anti-depressant just before approving Prozac and other tryptophan-like drugs."

The FDA cited the L-tryptophan situation in convening the Task Force whose proposals so horrified Fred Bingham. FDA Commissioner David Kessler cited a handful of toxicity reactions from the use of medical herbs under unspecified conditions. He also explained "[The] FDA is concerned about safety even though there has not been a large number of adverse reactions reported for these products," which he blamed on an inadequate reporting system. But George Carter of ACT UP/New York's Treatment and Data Committee countered: "These alleged safety concerns fly in the face of decades -- in some cases, centuries -- of documented safe use of these products. To the extent a product might produce toxicity at particular doses or in particular populations, that should be listed on the label so the consumer can exercise informed choice. But a ban viciously attacks that freedom to choose." And a ban would be particularly onerous -- and dangerous -- for PWAs who have so few effective treatment options to begin with.

FDA officials have denied that the Task Force recommendations represented current or planned agency policy. Yet the task force was composed of 12 top agency officials headed by the Deputy Associate Commissioner, and its report mirrors the last 30 years of FDA proposals to clear whole categories of nutitional supplements off the market -- efforts shot down by consumer firestorms, congressional action and adverse court decisions.

Meanwhile public confusion reigns about just what the FDA has proposed. Freedom of choice advocates charge that the Task Force's trial balloon on supplement safety was purposely floated alongside a new set of regulations on health claims. Mandated under the Nutrition Labeling and Education Act of 1990, the FDA drew up standards for judging permissible claims of disease prevention or treatment on food and supplement labels. Mainstream media coverage has focused on the labeling regulations -- for which consumer sympathy is easier to muster, given the cases of exaggerated claims -- while accepting FDA denials that it will implement the safety proposals (to ban products).

Under the new rules, in effect since June 1994, the FDA must clear all health claims on labels or in promotional literature for supplements. Any claim not approved is illegal and supplements bearing them can be seized from manufacturers, retailers or practitioners. At a meeting with AIDS activists in May 1994, FDA officials stated unequivocally that nonprofit buyer's clubs will be fully subject to the regulations. Says DAAIR's Bingham, "The FDA can use this power to prohibit AIDS buyer's clubs from circulating scientific information about their products to inform members about possible life-saving options."

In the past, the FDA has interpreted retailers' distribution of efficacy information -- even if published in a peer-reviewed medical journal -- as "making claims" and has seized products distributed alongside the literature. According to Lewin Usilton, director of the Healing Alternatives Foundation, a San Francisco AIDS buyers club, in 1988 an FDA agent spent four days inspecting their offices and photographing products to determine if claims were being made about the nutritional supplements sold there. An agreement was negotiated to physically segregate all scientific information about the products in a separate community library.

The regulations require the FDA to find "significant scientific agreement" on a health claim before approving it. Manufacturers have the burden of proof for a claim. Supplement advocates support helping consumers sort out the welter of health claims, but charge that the FDA has a 50 year record of dismissing the medical value of virtually all nutritional supplements. Despite hundreds of nutrient/disease relationships demonstrated in peer-reviewed medical literature, the FDA has only accepted two claims to date: that calcium prevents osteoporosis and folic acid prevents neural tube defects (brain damage) in embryos. The latter claim was approved in 1993, years after the CDC accepted it. At the same time, the FDA rejected -- despite considerable evidence -- five claims the U.S. Congress ordered it to examine, including connections between fiber and cancer, fiber and heart disease, antioxidants and cancer, omega-3 fatty acids and heart disease, and zinc and immune deficiency in the elderly.

Meanwhile an FDA fact sheet on "False Hope from Fraudulent Treatments" for AIDS lists as examples garlic pills, high potency vitamin supplements and such mood elevators or stress reducers as meditation, visualization and yoga -- despite small studies showing promising effects of each on immune functioning in HIV infection. What might be motivating the FDA's bias against nutritional supplements and alternative medicine in general? Many in Congress and public interest groups have noted the revolving door between top agency officials and the drug industry and have criticized the agency's failure to police unsafe drugs. In 1990, for example, Congress' General

Accounting Office (GAO) found that half the drugs approved by the FDA as safe later turned out to have common side effects so serious, including deaths, as to require relabeling or even withdrawal from the market. And a recent Johns Hopkins University study found that 500,000 Americans die annually from complications due to prescription drugs.

For years, holistic health advocates charged that the agency's actions against alternatives stemmed from a desire to protect the large pharmaceutical companies, a claim some dismissed as paranoid. But the report of the FDA Task Force revealed that it considered "what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive to drug development." And in a July 1993 speech to the Drug Information Association's meeting, FDA Deputy Commissioner for Policy, David Adams, warned that if freedom-of-choice advocates had their way, "there could be created a class of products to compete with approved drugt that are subject to less regulation [which] could undercut exclusivity rights enjoyed by the holders of approved drug applications." These statements, ACT UP's Onstott said, "clearly unveil both an FDA bias that assumes that pharmaceuticals are always superior to nutritional supplements as preventive/treatment agents and, more seriously, an FDA anticompetitive agenda favoring the drug industry over the supplements industry, at the expense of consumers' access to a range of health choices."

The Task Force's revealing statement fueled an already growing movement to check the FDA's anti-supplement actions. In May 1993, Senator Orrin Hatch of Utah, a state where several supplement companies are based, introduced the Dietary Supplement Health and Education Act. New Mexico Representative Bill Richardson soon followed suit with a similar version in the House. The core of the bill prohibits the FDA from reclassifying any vitamin, mineral, amino acid, herb or other nutritional supplement as a drug or food additive. The agency would attain clear power to remove unsafe supplements, leaving intact emergency powers for imminent health hazards, but shifting the burden of proof in long-term toxicity disputes from the industry to the FDA. Health claims would be permitted if they "accurately represent the state of scientific evidence," a lower standard than the "significant scientific agreement" required by new FDA regulations. The bill would also establish a small office in the NIH to research efficacy and safety of supplements.

Supporters of the supplements bill waged one of the most intense grassroots lobbying campaigns in congressional history. It was joined by many forces -- manufacturers, retailers and consumers of supplements, including a high-profile publicity campaign by health food stores. The result was Captiol Hill received more than one million pieces of mail about this bill -- outstripping every other issue -- and the bill was co-sponsored by large majorities in both houses.

AIDS activists were often at the forefront of the campaign. In June 1993, representatives of several AIDS groups, following a tense meeting with top FDA officials, formed the Consumer Coalition for Health Choices, independent from the industry, to defend access to supplements. Ultimately a dozen grassroots organizations, including four ACT UP chapters, three AIDS buyers clubs, the California delegation of the National Organization for Women (NOW) and advocacy groups for people with cancer, Alzheimers and sickle cell anemia joined the coalition.

But not all AIDS groups supported the bill. Some were made uneasy by the prospect of groups with large gay memberships supporting a bill sponsored by Orrin Hatch. Others had specific reservations about the bill. Derek Hodel of AIDS Action Coucil, a Washington-based lobby network, sent Hatch a letter (co-signed by five other members of the Treatment Action Group and listing their affiliations with other AIDS groups) expressing their concern that the bill "proposes shifting the burden of proof of safety from the manufacturers to the FDA, which we believe could seriously compromise consumer safety." In addition, the letter argued that the bill's "markedly more lenient" standard on health claims "may serve to further confuse consumers by establishing a standard that is inconsistent with those already in use."

Still other AIDS groups found fault with both sides' position. PWA Health Group Executive Director, Sally Cooper, wrote in the group's newsletter: "As if six years of rampant profiteering by drug companies wasn't enough. PWAs seem to be caught in the middle of another right-wing dog fight, reflecting opposing market interests. It's easy to agree that some regulations (and research) is reasonable and long overdue, but difficult to agree that the FDA with such a long history of biased and irregular enforcement practices should be the ones to do it. It's upsetting that no one -- activists, holistic practitioners, FDA staff or congressional representatives -- is working on improving what everyone off the record agrees is not a good system."

In fact the Consumer Coalition is doing just that. To make the bill more consumer friendly, it has proposed amendments providing the FDA power to order warning labels for products with general toxicities or contraindications for specific at-risk groups; tighter restrictions on false industry claims; a commission of scientists, practitioners and consumers to guide and oversee FDA actions on health claims and safety issues; and an ombudsperson's office for consumer complaints -- against either the FDA or the industry. Says ACT UP's Onstott, "Although the bill began as part of the industry's agenda, these amendments, if adopted, will bring it in line with the true needs of consumers, including people with HIV."

In May 1994, a slightly modified bill passed the Senate Labor and Human Resources Committee. It seems certain to pass the full Senate. But, on the House side its prospects are cloudy. The Health and Environment Subcommittee which controls the bill is chaired by California Representative Henry Waxman. While a supporter of the AIDS community on many issues, in this case Waxman has repeatedly backed the FDA, arguing that the agency does its job fairly. He has refused to release the bill, despite majority support in his subcommittee. Freedom of choice advocates charge that his hard line may be influence by more than $1 million in campaign contributions in the last 12 years by political action committees (PACs) of doctors' associations and drug companies. Numerous demonstrations have occurred outside Waxman's district office and several of his Hollywood financial backers have implored him to change his position; so far, to no avail.

As the vitamin wars move toward their inevitable showdown, the question people with HIV and AIDS are left with is: What will it all mean for me? AIDS activists on both sides hope that either way, the result will ensure that supplements are safe and honestly labeled, while freedom of informed choice is maintained. The lives of PWAs may very well depend on it.

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