U.S. Dietary Law Is Undermining Public's Health

Consumer protection, a colleague said recently, is dead!

He's right.

No better example of hucksterism's triumph over consumerism can be found than the continuing erosion of federal laws and rules that protect the safety and integrity of the food we eat and the drugs we take.

This damage is clear-cut in a newly released federal document called the Draft Report of the Commission on Dietary Supplement Labels; it was prepared for the Department of Health and Human Services (HSS). The panel is composed of scientists, a lawyer, and industry reps, including the president of the Herb Research Foundation of Boulder, Colorado.

The Commission was created under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which advanced the interests of the health food industry and the many Americans who dote on vitamins, amino acids, botanicals and the myriad of other consumable products sold at GNC (General Nutrition Center) outlets and other health food stores.

The locus of this effort is the Federal Food, Drug, and Cosmetic Act (FDCA), as amended, which was signed into law in 1938. The Senate defined a drug as a substance "intended for use in the cure, mitigation, treatment or prevention of disease," or "intended to affect the structure and function of the body."

The FDCA, with later amendments, stipulates that in order to be sold in interstate commerce, a drug has to be shown scientifically to be safe and effective for the purpose designated on the label. If a medicinal claim is made for any product — "Cures hangnails," for example — the manufacturer must convince the Food and Drug Administration (FDA) with rigorously conducted studies that the substance safely and effectively does what is claimed for it. This landmark, fortunately, still stands in the law.

By contrast, no such proofs are needed to sell ordinary food products.

This arrangement has dictated strategy for the tens of thousands of manufacturers, processors, and dealers who want to sell products that can't meet FDA's drug test, but which — they claim — will relieve or cure all manner of illnesses, including heart attacks and cancers: Sell the stuff as foods, not drugs, by continued on page 3

Press Catered to Cig Makers

Tobacco Greed, Guilt Widely Shared

We've not been a major journalistic player in the smoking story, now coming to a head. We have, however, placed a few lances (PROBE, April '96, for example).

We started PROBE partly because we couldn't speak truth about smoking in the mainstream media, where we were, for one thing, the Ladies' Home Journal health columnist for more than a dozen years. By the time we started, in the mid-60s, there was no longer any doubt that cigs were killers — though how, and how many they killed remained unclear.

When cig ads were forced off radio and TV, in 1971, the tobacco companies switched to print, particularly in the women's mags, where they promoted Eve and Virginia Slims, as well as their standard brands. The American Cancer Society (ACS), meanwhile, courted the Journal's publisher — they put her on a board and gave her an award. But the Journal, like all the women's mags (with the honorable exception of Good Housekeeping) continued to take cigarette ads and censor its writers' cigarette coverage. Not surprisingly, lung cancer soon topped breast cancer as the leading cause of cancer deaths in American women.

One year, we wrote a tiny item about cancer and cigs for the Journal and were rewarded by a phone call from our editor: "Count the ads, David," he admonished. "Count the ads!"

There were, we recall, 13 plus pages of them that month. Needless to say, our anti-smoking squib never ran. But it continued on page 3
**Follow-up**

**Shalala Dismisses Naderite Petition**

In our last issue, we described a petition by physician Sidney Wolfe, M.D. and several associates at the Public Citizen's Health Research Group, in Washington, D.C. — an organization linked to Ralph Nader. They had alleged that U.S.-sponsored drug trials on pregnant HIV-positive women in Africa are unethical.

They demanded that the studies be stopped. Reason: The women are not all given the U.S. standard of care, an AZT regimen for mother and child that is proven effective, but costs at least $1,000.

Since few if any Third World women can afford this, the current studies use lesser, cheaper drug regimens. Researchers hope one can be found that is both effective and affordable for the Third World.

At our press time, HHS Sec. Donna Shalala, to whom Wolfe et al. sent their plea, had not replied. She now has, in a "Dear Sid" letter dated July 15.

After chiding Wolfe for going over her head, and sending a follow-up plea to her boss, President Clinton, Shalala says that she had asked National Institutes of Health chief Harold Varmus, M.D., and David Satcher, M.D., who is the head of the Centers for Disease Control (CDC), in Atlanta, to study Public Citizen’s charges. She tells Wolfe in her response that they found the clinical trials to be ethical and appropriate — as well as badly needed — as she herself does.

They have concluded, she writes that "researchers in the host [Third World] countries and the U.S. are carrying out scientifically meritorious and ethically sound experimental designs, providing effective protection of human research subjects, and faithfully adhering to approved research protocols that are consistent with the recommendations of the World Health Organization and approved by all of the countries involved."

In short: Objection dismissed.

We’re not surprised. Our unanswered questions are why Public Citizen would embark on such a dumb and futile campaign, and why our colleagues — particularly CNN — would hype it.

We’re waiting to see if CNN tells its viewers what happened to Wolfe’s petition. As of July 25, we had not seen a follow-up report on CNN.

###

**Deadly Teas:** Ever since his wife, June, 37, died after drinking Laci Le Beau Super Dieter’s Tea, San Francisco attorney Christopher E. Grell has fought to ban it, and similar products. They contain medicinal amounts of powerful laxatives, yet are marketed loosely, as nutritional supplements (PROBE, May ’94). Grell thus far has not been able to get these products banned as mislabeled drugs; a new so-called “nutrition education” law has crippled U.S. Food and Drug Administration (FDA) efforts to regulate these products. (See story, p.1.)

Nevertheless, Grell and his supporters have been successful at the state level in providing partial control of Laci Le Beau teas and similar products that contain senna (Cassia angustifolia), aloe, buckthorn, frangula, rhubarb root, and other gut "cleansing" substances. California, in the lead, now requires this product warning:

**NOTICE:** This product contains (name of ingredient). Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.

California is a major market for herbs and similar health products. So this labeling requirement is a large step forward. What is more, when we checked out the Laci Le Beau products at our corner health food store, in Manhattan, we found the same warning.

Consumers have reason to thank Chris Grell for his persistence in transforming the pain of family tragedy into protective public policy.

###

**Fed Stalls on Stadol:** We reported in January that the Fed — in this case the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) — had agreed to list the prescription pain-reliever butorphanol (Stadol, Bristol) as a controlled substance. This means a doctor would have to use a special triplicate federal form to prescribe it. These “scripts” are monitored by DEA, and adding Stadol to its schedule IV, of continued on page 8

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Tobacco...
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seemed to us then, as it does now, to be a travesty to write about women's health, and deal with cracked toenails and menstrual cramps, while remaining silent about the dangers of cigarette smoking.

Why Settle?
What, finally, forced the cig merchants to seek a settlement? Our guess is that the Justice Dept. was, and may yet be, working on perjury indictments for the company presidents who lied to Congress under oath about cigs' hazards a couple of years ago.
The prospect of jail, we believe, is the lever in the proposed deal — and the fed should not let go of it.

As the story has developed — dramatically — in the news, we've been reading two books on tobacco. One is our colleague Phil Hilt's Smoke Screen (Addison-Wesley, 1996), on the British-American Tobacco papers that were leaked to the New York Times in 1994. Phil's book is crisp and gripping.

A longer, more leisurely read is Richard Kluger's Pulitzer prize-winning cigarette history Ashes to Ashes (Knopf, 1996); it rolls on for 800 pages, and is an excellent backgrounder to the current tobacco news breaks.

He demonstrates clearly that the cig companies and their executives have long known their product's hazard to health, and have conspired to conceal it from the public, the govern-

Dietary...
continued from page 1

taking the claims off the labels. Instead, make these claims in leaflets, magazines, books, and by word-of-mouth in health food stores and the community at large, using radio and TV talk shows.

Federal legislation in the early '90s facilitated this effort by legalizing FDA-approved "health claims" for some conventional foods and dietary supplements. These include:
• Folate will prevent neural tube defects [spina bifida].
• Calcium will help prevent osteoporosis.
• Polyunsaturated fats will help prevent cancer.
• Fruits, vegetables, and grain products containing fiber, particularly soluble fiber, will help prevent coronary heart disease.

Each of these health claims, however, required much scientific research, and cost millions to prove to FDA's satisfaction. This is more than most herb and supplement sellers are willing to gamble on their products. The 1994 DSHEA, for which they lobbied intensely, opened the way for them to sell "dietary supplements" and "nutritional supplements" that are neither ordinary foods nor drugs under the FDC Act. It stipulates that health-related, but technically non-medicinal claims can be made on the basis of evidence that would not meet FDA's more stringent requirements for drugs or proven supplements like folate.

Quackbusters on Call!
We — meaning America, and perhaps the whole globe — are overrun by quacks, shills, and charlatans. Why is a focus of PROBE's coverage.

We cannot, however, and do not see it as our mission to keep track of all the healthcare phonies who come down the pike. Fortunately, there is a far more knowledgeable person available — and there is little about health and medical fraud that he doesn't know, or can't find in his voluminous files or from his close colleagues.

This Quackbuster is retired psychiatrist and current consumer advocate Stephen Barrett, M.D., of Allentown, Pa. He can be reached by e-mail at sbinfo@ix.netcom.com.

We urge PROBE readers who have questions about possible quackery — including cancer treatment frauds — or information about them that they wish to share, to contact Steve on the net. He also can be reached by phone.

— D.R.Z.

August 1997
Dietary...
continued from preceding page
means there now are (at least) four levels of products:
1. drugs, regulated by FDA
2. dietary supplements, regulated by FDA
3. nutritional supplements (new), which are not regulated by FDA
4. foods, regulated by FDA
The 1994 Act thus is an end run around FDA’s longstanding consumer protection. It does come at some cost to these products’ sellers and buyers: Product labels for the newly defined supplements must carry a disclaimer:
“This [label] statement has not been evaluated by FDA. The product is not intended to diagnose, treat, cure, or prevent any disease.”

Caveat emptor!
But of course these products are being sold precisely for the purposes just listed!
These new claims are designated by the DSHE Act as “allowable structure/function statement[s] of nutritional support,” which is to say, according to the Commission, a claim “that is clearly not a health claim and not a drug claim.”
What it is, or might be, however, “has never been specifically outlined in either legislation or regulations,” the panel acknowledges.
The Commission also acknowledges that its seven members had significant difficulty in sorting out, in their own minds, the differences between a “health claim,” regulated by FDA, and a “structural/functional claim,” which is to be regulated by an as-yet-uncreated HHS Dietary Supplements Office, and also, in part — in case of an imminent health threat — by FDA. Is a claim such as “reduces heart rate” a health claim, or a supportive structural/functional nutritional claim? the Commissioners asked themselves.
If these well-informed panelists couldn’t figure it out for sure, it is hard to know how the average consumer can. It seems unlikely, too, that very many of us will be able to identify a particular claim — as “drug,” “health,” or “structural/functional support” — and understand, too, which degree of scientific validity, if any, it represents.
This muddying of the waters is of course exactly what the junk sellers sought. It creates a huge gray area between drugs and foods, within which they can promote and sell their unproven products.
The best solution would be to repeal the 1994 Act, and start over. That is unlikely to happen.
These merchants are busily making drug — that is to say, medicinal — claims for their unproven products. Why would anyone buy them if they weren’t?

# # #
Disclosure: This writer is the author of Zimmerman's Complete Guide to Nonprescription Drugs (Detroit: Gale, 1994), which evaluates the medicinal, but not the “nutritional” use of some herbal products.

Time’s Health Tome Disregards Science
For several decades, Time Life Books (now part of Time-Life Warner) has supped at science’s table — and at medicine’s, too. No media group has been as aggressive, or as skilled, as Time-Life in telling the public about biology, astronomy, and space, as well as dramatic medical advances.
Now, however, while some of this excellent coverage continues, Time Life Books has stabbed science and rational medicine in the back. It has published a volume of holistic hogwash called The Alternative Advisor: The Complete Guide to Natural Therapies and Alternative Treatments. This book describes and validates the whole gamut of cultish but unproven therapies, ranging from acupressure and aromatherapy through homeopathy and mind/body medicine, to t’ai chi and yoga. They are simplified, prettified — and recommended for a wide range of illnesses, up to and including heart disease and cancer.
We are unaware of any alternative treatment in this 400-page, $25 compendium that has been shown to be safe and effective, using scientific standards.
"Time Life has gone herbal," babbles a news release for the book from Rentsch Associates, a New York P.R. agency. "[It’s] a natural move... . Mainstream America is riding an alternative tide as more and more people look for trustworthy, user-friendly medical information for their homes."

Data Are Questioned
The “information” in the book is mostly specious; some is dangerous. Time Life protects itself with a standard up-front disclaimer: The guide is “a reference source only.”
Bottom Line: We think people are foolish to rely on quack remedies, even those touted by Time Life, when safe and effective prescription and nonprescription drugs are readily available for the same purposes.

Time Inc. Acquires Alternativist Web Site
The New Media Division of Time, Inc. has obtained the Website "Ask Dr. Weil" for its Pathfinder Network (http://pathfinder.com), the company has announced. The site is operated by University of Arizona alternativist physician Andrew Weil, M.D.
Time says it is the “premier health site on the World Wide Web.”
The Time, Inc. editor who produces this website declared: "We know what our audience wants, and we’re going to deliver it."
Indeed! — D.R.Z.
Introduction

The Supreme Court has just ruled 6 to 3 that illegal ritual practices that are sacred to religions — such as Native Americans' use of peyote or Catholic children's partaking of wine at Mass — cannot be protected by special laws. This decision exposes the growing conflict between our secular American nation and a myriad of religious and cultural groups that claim a constitutional right of religious freedom to express their beliefs, even when they conflict with the law.

Religionists and civil libertarians have denounced the Court’s decision striking down the Religious Freedom Restoration Act, which was signed into law by Bill Clinton four years ago. They have set about to re-enact it in a way the Court will accept.

Many of the controversial practices involve health and medicine. For example: Lawyers for 12-year-old Malcolm Shabazz, of New York, who fatally torched his grandmother, educator Betty Shabazz, Ph.D. (Malcolm X’s widow) demanded, successfully, that her body not be autopsied, as required by law in homicides because her religion — Islam — forbids it. Orthodox Jews demand similar exceptions.

The most distressing non-western custom, female genital mutilation (FGM), has now been banned by federal law, albeit compliance remains uncertain. If the Fed can ban FGM, can Moslem girls be prohibited from wearing the chador to school? What about yarmulkes? Or crucifixes?

Clearly, the line between secular values and religious rights is hard to draw!

Many of these conflicts came to a head earlier in our sister constitutional democracy, France. Thinkers there have already confronted them. One Parisian philosopher who frequently speaks and writes on these issues is Alain Finkielkraut, the descendant of Lithuanian Jews, who first won fame as Jean-Paul Sartre’s secretary and protégé. (We presented some of Finkielkraut’s views in our October ’95 issue.)

We discussed these secular/cultural issues with Finkielkraut in a tape-recorded interview, on the occasion of Columbia University’s publication, in translation, of his Defeat of the Mind (La Défaite de la Pensee). A paperback edition is now available for $15.

We’re publishing this interview here for the light it sheds on current U.S. concerns. PROBE readers are invited to comment.

— D.R.Z.
So it harms our values and our secular tradition. We have a very important tradition of secularism in France — and either we convince this girl, or her parents, that it’s for the sake of universal value that they have to take off the veil. Or, we don’t, and if we don’t, we just have to say:

“That’s the way it is here. This is our law and our tradition, and you have to comply with them!”

The problem, however, is not only with the new religious movements we see all over the world. The problem is with the sociologists and anthropologists who support these movements because they believe in culture, or because they believe in facts. Right now, that’s a problem for us in France. It’s also a problem for you in the U.S.

PROBE: Proponents of FGM and their multiculturalist supporters claim, Alain, that, as a cultural and religious practice, it should be of no concern to the state or other people. It should be protected. Why do you disagree?

FINKIELKRAUT: I disagree because this religious and cultural practice contradicts other values that belong to the positive realm of the law. We must make a choice. But we cannot defend, at the same time, the sanctity of culture and the sanctity and freedom of the person.

Our choice has already been made. In our countries we have had to fight against our own tradition, our own culture, to protect the freedom of the individual, to achieve equality.

The world we come from was heretical.

In the 18th century, there were people who said, “Well, it’s our tradition. But we don’t believe in this tradition any more. We are going to create something new!”

If there hadn’t been such people, you know, who were sufficiently disrespectful of their own traditions, then we wouldn’t now benefit from the Declaration of the Rights of Man. We do benefit, because these people were strong enough to emancipate themselves from their own cultures. And this strength, this fight, does not then have to belong solely to white men.

PROBE: Everybody can learn to enjoy it?

FINKIELKRAUT: Everybody can enjoy! Especially in a country where these rights are protected.

PROBE: So you’re saying there is a deeper, more fundamental issue, of hegemony, that concerns individual rights on the one hand, and group rights and hegemony on the other. And what you’re saying is that as thoughtful men and women at the end of the century and of the millennium we should be concerned — very concerned — about this conflict. You have said that this is the essential conflict of our time. Is it?

FINKIELKRAUT: Now, I would express myself this way: The essential conflict is between people who stick to their cultures so tightly that they won’t let people be. They refer to their culture to forbid any kind of freedom. On the other hand many people submit to mass culture — and so cannot use their freedom. This is a new dilemma.

PROBE: What are the legal bases of individual rights and hegemony in France and in the U.S.? What are the documents? Is it the Declaration of the Rights of Man?

FINKIELKRAUT: Well, we have the Constitution, because the Rights of Man have been constitutionalized in France. So we have that. And in America, I think you have the same thing: You have the Constitution; you have your First Amendment; and so on . . .

PROBE: The Bill of Rights . . .

FINKIELKRAUT: . . . and the Bill of Rights. And I think that it’s more than enough.

PROBE: Can you name, briefly, some of the other ideological and political threats to freedom, in this country, as you see them?

FINKIELKRAUT: Well, as a visitor I . . .

PROBE: You mentioned mass culture.

FINKIELKRAUT: But that’s everywhere. I think it’s more of a problem, maybe, in America than anywhere else. But Europe is now making up for lost time, and it will be even worse shortly. Not only is it a threat to freedom, but it’s a threat to the commonwealth.

PROBE: Yes.

FINKIELKRAUT: Commonwealth is the word I want to use, because it’s the meaning, the political meaning, of a nation. The ability to form a commonwealth, and the idea that we belong to and take responsibility for it — I think this is fading away.

I was struck, of course, by what happened in the O.J. Simpson trial: The fact that he was acquitted; the split between the black and white people; and the idea of the blacks that, well, he must be innocent because the white police and white justice like to convict and sentence black people. So, if we are in a white country and if a black is accused of murder, he must be innocent.

This kind of reasoning strikes me as very threatening. Because people are not interested in facts anymore. They all
As the Core Western Value

have their own identities, and they do not really belong to the same world. And, facts don’t count.

The split in the society is something very, very bad — something that I am frightened of here in America. The only thing that truly unites people is politics. It’s not culture.

If you have this kind of fracture in a society, and nothing to unite people except the cultural industry, then well, things are going wrong.

PROBE: What can and should we be doing in our universities and other schools to counter this trend?

FINKIELKRAUT: The first thing to do, I think, would be to resist any kind of intimidation by the multicultural movement and by political correctness. Professors should resist the politically-correct movements that we now face in the universities. Culture today just aggravates, intensifies the split between people. So the blacks in school are taught to think black, and the women, to think, well, womenly, and so on. When you go to bookstores you see huge spaces for gay and lesbian studies, and then others for Afro-American studies — it’s a very, very serious problem.

This has nothing to do with culture anymore and a lot to do with propaganda. The idea is that everyone is a racist, and that you go to school to be cured of your racism.

But you can’t fight racism that way. The idea is that there are two kinds of people in this country, majority people who are racist; they have to be cured of their racism so they go to school to be opened to the problems and the existence of the others. Second, there are all these others, all these minorities.

The minorities have to be ready to be re-legitimated in order to regain their self-esteem. So, in school, people show them all kinds of books that present these minorities as good people. So they feel better. It’s as if culture was a part of what Charles Taylor calls “the politics of recognition.” The main concept of culture becomes recognition, and recognition replaces — and this is very dangerous — conversation. It’s recognition versus conversation.

Conversation with the great texts! This conversation can nurture the conversations people have with other people.

But now it’s no longer a question of conversation. It’s a question of recognition. We white males have to recognize the blacks, the gays, the lesbians, the women, the Chicanos, etc. That’s become the only acceptable subject of literature — and in this, I think, the destruction of culture is under way.

So: Our task as professors is to reestablish culture as conversation against culture as recognition.

PROBE: So how do concerned individuals express their support for liberty, for equality, for conversation, for fraternity, for constitutional freedom in a world in which the culturalists and the multiculturists are self-appointed keepers of the geist — and more and more seem to hold sway. How do we do this?

FINKIELKRAUT: I don’t know! I have no solution! It is kind of an ideological fight now . . . .

I don’t know who is going to win. But, we cannot avoid involvement in this struggle.

Of course, it would be dangerous to be too contemptuous, to speak too disparagingly of the geist. I agree that there is a [cultural] richness that we all belong to. We all inherit something. We all come from somewhere . . . . So uprootedness is not the ideal.

We are heirs of the Enlightenment. We also are heirs of Romanticism. That’s a double philosophical inheritance. That’s the uneasiness of being modern. It’s not possible to banish one heritage for the benefit of the other. We have to assume and bear them both. That’s our patrimony, that’s our twisted and splintered patrimony. That’s our philosophical condition.

So, I don’t want to be too contemptuous of what is called “the geist.” But, still, the magical use of it in the realm of education has nothing to do with real romantic and philosophical meditation. It is ideological, it is propaganda, and it destroys the human link instead of nurturing and legitimizing and deepening it.

We have to deepen this link, because otherwise, the only connection between all people will be the advancing mass culture.

We’re living in a very strange world, because it’s a world of freedom, abundance, richness, for America, for France, and for a few others. Yet the general level of culture, instead of rising, is declining.

It is decreasing more and more.

None of the philosophers of the Enlightenment could foresee such a strange and paradoxical future. When you see professors participating in this movement, helping this movement with magical control fantasies, it really is striking! It’s also revolting — and it makes me indignant. We have to do the opposite right now!

PROBE: What I wanted to get out was, Are there any organizations that oppose this multicultural view? Or are we all just individuals?

FINKIELKRAUT: Mostly I have seen individuals trying to resist the zeitgeist. I don’t see organizations or movements doing it.

This resistance is very difficult. You know, people are afraid to think. This reduces reality to simplistic judgments. That’s the real support of the multicultural movement. That’s why only individuals, I think, resist. Not organizations.

PROBE: Thank you.
Follow-up...

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potentially dangerous substances, would predictably reduce the number of scripts and sales — which are running at about $200 million per year in the U.S. This also would cut Bristol's profits on the $70-a-bottle "narcotic," which is formulated as a nasal spray, and so is easy to self-administer: No needle or injection is needed.

The federal agencies were prodded to act by Evanston, Ill., neurologist Morris A. Fisher, M.D., whose son, Bruce, a Stadol addict, put a shotgun barrel in his mouth two years ago, and pulled the trigger. Fisher and government officials told us that federal action was in progress. But, months later, it hasn't happened, Bristol still promotes the drug, with few additional warnings. According to our Boston colleague Richard A. Knox, in the Globe (May 27), neither agency has warned doctors or patients about Stadol's dangers. Knox quotes FDA official Nick Reuter, as saying: "I'd be hard pressed to say what our threshold was, but we haven't met or reached it with Stadol."

The drug is mostly prescribed for migraine sufferers, who find it very effective in relieving their pain. But some, like Bruce Fisher, become hooked. He killed himself, his father says, when doctors realized he was addicted, and stopped writing him Stadol prescriptions. Bristol, which at first strongly opposed tighter controls, now says it petitioned the Fed to "schedule" the drug two years ago.

Why is the government dragging its feet? We don't know. But it strikes us as still one more example of the paralysis that has gripped Sec. Donna Shalala's Health and Human Services Department and much of the rest of the Federal government. ■

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