Exclusive:

How Dying Patients Are Gulled: Ads ‘Misrepresented’ Outcomes

People with cancer who’ve been given bad news by their family physician or local surgeon are rightly frightened — and may be ready to grasp at any straw. They may come across testimonial ads published in the New Yorker, Parade, Reader’s Digest or other media outlets in which a vibrant young person tells how he or she has been saved by treatment programs at one of two hospitals, in Zion, Ill., or Tulsa, Okla. These hospitals provide “holistic” cancer care. The ads carry an 800 number — currently 1-800-392-5055 — and callers speak to hospital representatives, who may send them a brochure describing the treatment centers, the services offered, and the qualifications of their medical staffs (See box, p. 7).

The companies that promote and provide these services operate under the trade name Cancer Treatment Centers of America (CTCA), of Arlington Heights, Ill. The ads help generate business for CTCA: Sales in the early 90s were reportedly in excess of $40 million continued on page 6

FTC Analyzes CTCA’s Claims

How can a sick, frightened person and his or her family judge the claims made by a cancer care provider? It can be very difficult, and for some claims, nigh unto impossible, FTC staff attorneys say in memoranda on their investigation of Cancer Treatment Centers of America (CTCA).

The FTC’s reasoning, based on analysis of material provided by CTCA to back its claims, indicates the kinds of questions that consumers, like FTC staffers, might ask in assessing an alternativist — or for that matter, a conventional — cancer care provider’s claims. CTCA has been ordered by the FTC not to repeat some of the false or unsubstantiated claims it had been making. But other, perhaps less scrupulous care providers may — and undoubtedly will — make similar claims. The FTC’s consent agreement with CTCA and the analyses that led up to it thus may be useful guides to ill Americans who face similar dilemmas — which is why we are describing them here:

“Statistically, our five-year survivorship is among the highest documented.”

This claim was made in a sales brochure, which CTCA said was discontinued before FTC began it probe. FTC rejected this excuse, and requested the “documented” data.

“CTCA either could not or would not provide data,” FTC says, and CTCA protested that it would be bad policy for the agency to rule on a voluntarily discontinued claim. FTC reprints a quote from a Dallas Morning News interview with CTCA senior medical director R. Michael Williams, M.D., an oncologist, who “acknowledged that he can’t scientifically prove their patients live longer or live better than those who go elsewhere.”

In responding to an earlier probe, by the Texas Attorney General, CTCA said, “[i]n dealing with advanced cancer, it is inappropriate to speak of ‘cures’ . . . or ‘cure rates.’ Most of the time all that is available is a number of treatments which provide responses and benefits some of the time.”

Proof Withheld

CTCA failed to provide documentation for its survival rates, the FTC staff said, suggesting that the treatment group “chose to ‘surrender’ on this issue, rather than to permit their actual survivorship rates to be discovered.”

“We conclude,” the FTC lawyers write, in a November 23, 1993 memo to the chief of FTC’s Bureau of Consumer Protection, “that CTCA lacked a factual basis for the claim that its five-year survived on page 6
Naderites Blast AIDS Studies; CNN Buys in: Coverage Is Slanted

We’re never sure. Are physician Sidney M. Wolfe, M.D. and his Public Citizen’s Health Research Group cynical? Or dumb? Or both?

We are surprised, however, that CNN, a nominally careful and very conservative news organization, would swallow one of Public Citizen’s anti-science red herrings — hook, line, and sinker.

The case in point: Wolfe’s group, which was founded by Ralph Nader, has attacked — as unethical and horrific — a series of anti-AIDS studies that U.S., European and international agencies, including the UN, are conducting in Africa and other Third World nations, with these nations’ cooperation. The studies, on some 9,000 pregnant women, are designed to find practical and feasible ways to stop HIV (human immunodeficiency virus) from passing from mother to fetus or child; the protocols have been approved by institutional and governmental review boards in the sponsoring Western nations and in the recipient developing ones. Nevertheless, Public Citizen equates these studies with the notorious Tuskegee syphilis study, which has lately been back in the news.

Script Is Printed

The following is CNN’s April 22 report on Third World AIDS experiments:

Anchor: The U.S. government is paying for unethical AIDS experiments abroad that could take the lives of about 1,000 children. So says a consumer group that investigated the research, as CNN medical correspondent Jeff Levine reports.

Jeff Levine: It’s well-known that the drug AZT dramatically reduces the chances a pregnant woman will pass the AIDS virus on to her unborn baby. So a consumer group wants to know why the U.S. government is paying for experiments in poor nations that deprive some pregnant women of AZT or something equivalent.

Peter Lurie, M.D., Public Citizen: It’s certainly as bad as anything that has occurred since World War 2 in terms of the violations of the basics of medical ethics. Many people are hearing in this echoes of the notorious Tuskegee Syphilis Study.

Levine: In [it], African American men with syphilis were denied effective treatment for decades. In this case, Public Citizen charges, women in Africa, Asia, and the Caribbean are also being exposed to unethical and indefensible experiments. The concern: Some are being given dummy drugs or unproven treatments — something that Public Citizen says isn’t happening in comparable studies in the U.S. The organization is demanding a government investigation for possible criminal violations.

Sidney Wolfe, M.D., Public Citizen: These experi...
Script...

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ments are horribly, dangerously, fatally flawed, and should not have been done.

**Levine:** Public health officials defend their experiments on the grounds that AZT is too expensive for most patients in developing countries. And, such novel approaches need to be studied to see if they are better than nothing.

**Helen Gayle, M.D., Centers for Disease Control:** In the countries that we’re talking about the health care expenditure is about $10 per person per year. So it’s really important to make sure that what we’re looking for as a potential outgrowth of this is something that is really relevant and affordable.

**Levine:** Public health officials say that’s simply not possible, given the economic and cultural obstacles they face. In fact, they insist, it would be unethical to test an approach they could never put into practice. I’m Jeff Levine, CNN, Washington.

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Jeff Levine Replies

We faxed a copy of our critique to Jeff Levine at CNN. These are key points in his reply:

“Did we slant the story? I think a cursory reading of the script puts that notion to rest. We recapitulated the Public Citizen argument, then set out to get a government rebuttal — something that proved difficult. However, we ultimately succeeded.

“In sum, public health officials acknowledge that there is indeed a difference in the way trials of AZT in pregnant women are conducted overseas. Government researchers believe they are doing the right thing because in poverty-stricken countries it’s important to know if minimal interventions will work. The real issue here is whether the means is justified by the end of coming up with treatment variations of AZT, if that’s all a nation can afford. . . .

“Should we [CNN] have dismissed the [Public Citizen] accusation? This was a serious charge by a reputable organization with a track record of uncovering fraud and misbehavior in the medical profession. For us to ignore [its] report would be a violation of our journalistic responsibility.”

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CNN...

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Wolfe charges. Levine states that the Third World women are not getting AZT. This is thoroughly deceptive, since few if any of these women would get the drug if they weren’t in the study. What is more, half of the women do get the drug — which otherwise almost certainly would be unavailable to them.

Levine says there is “something equivalent” to AZT. But there isn’t.

It is a fatal flaw, journalistically, for Levine and CNN to withhold the news that “the novel approaches” that are being studied are, in fact, AZT, albeit in experimental low doses. And it is thoroughly irresponsible to report reproachfully, as Levine does, that these approaches “need to be studied to see if they’re better than nothing,” when in fact this is precisely what CDC and the other agencies targeted by Wolfe et al. are doing!

This is outrageously bad and deceptive reporting!

**Story Choice Questioned**

The more basic question is why CNN decided to do the story in the first place. The New York Times checked it out, a government source tells us, and decided — wisely — to ignore it. The Washington Post ran an analytical piece by Abigail Trafford (May 13) that led with Public Citizen’s charges, then asked: “But is this really Tuskegee Redux?”

The Post’s answer is: No. It is not “Tuskegee Part 2,” as alleged.

Unlike the Post, CNN appears not to have questioned the charges. Reporter Jeff Levine does interview pediatrician Helene Gayle, M.D., who directs the CDC studies — but this soundbite comes late in his brief, two-minute piece. It thus seems to be a pro forma denial of wrongdoing, not the substantive judgment that she — and we — think it is.

Similarly, Levine closes, lamely, with the CDC’s position. But, given the incendiary linkage of Tuskegee and the current AIDS studies in (mostly) black people, this realistic rationale is not likely to impress some viewers.

**Credibility Is Issue**

Obviously, viewers will say to themselves, CNN wouldn’t have put it out if it wasn’t credible. What is more, most Americans, and particularly black Americans, recall that it is the same linked agencies, CDC and the U.S. Public Health Service, that, in fact, conducted the Tuskegee experiment. Never mind that times and institutions have changed. CDC, which certainly was racist then, is currently headed by a black physician, David Satcher, M.D., who is being groomed to be the next Surgeon General!

CNN’s coverage thus reifies Sidney Wolfe’s wild style of attack — against research, doctors, and of course drug companies — which in turn resonates with many Americans’ anti-establishment anger. The coverage thus legitimates the style and substance of Public Citizen’s logically flawed and unrealistic attack.

— D.R.Z.
Public Citizen’s Seriously Flawed Trials

Behind CNN’s brief, biased report on Third World AIDS drug trials, described on pages 2 and 3, lies Public Citizen’s logically and, we think, ethically flawed effort to derail these studies. The group’s petition, in April, to Health and Human Services (HHS) Secretary Donna Shalala, is thoroughly unrealistic and lacking in medical and common sense. Reading it is like travelling through the Looking Glass with Lewis Carroll.

The starting point is the discovery three years ago — through a double-blind, placebo-controlled U.S. study called Protocol 076 — that intensive treatment of pregnant HIV-infected women and their new babies with the drug AZT will significantly reduce the babies’ risk of HIV infection. Only 7% of the neonates end up infected, compared to 22% without AZT.

Protocol 076 has now become the standard of care in the U.S. Gratifyingly, far fewer HIV-infected babies are now being born.

This treatment, however, costs over $1,000. It requires elaborate pre-natal, obstetric, and post partum care, that, realistically, is unavailable in much of the Third World. Protocol 076 simply can’t be provided there as standard care, and would be difficult and costly to provide even in experimental studies.

Cheaper Regimens Sought

This conundrum has stimulated more than a dozen international studies to find easier ways to block mother-to-child HIV infection. Some of these studies employ smaller, briefer, and hence cheaper AZT regimens; others have looked, without success, at washing the mother’s vagina with an antiseptic, treating her with anti-HIV immunoglobulin (immunotherapy), or treating mom and/or baby with vitamins.

The most promising of these studies thus far may be the ones using the low-dose regimens of AZT. Current U.S. and international thinking is that an AZT regimen that could be provided for $50 might be feasible and practical in the Third World — if one can be found.

Most current studies to develop it are sponsored by CDC, the National Institutes of Health (NIH), both parts of HHS, or by Johns Hopkins University or European governments and research agencies, or by the UN. Most are placebo-controlled: Half the women who sign up are randomly selected to receive low-dose AZT regimens. The others get inert, dummy medication.

Violations Charged

This is the source of Public Citizen’s complaint:

They claim it is unethical — as well as immoral and illegal under the Nuremburg Code and other international treaties that protect research subjects — not to give the controls any medication, even though, outside the studies, they wouldn’t get any either. (Obviously, an HIV-positive African woman who suddenly comes into the cash needed for the U.S. “standard” AZT regimen, Protocol 076, has but to pay for it, and tear up her clinic card.)

“Those experiments are in clear violation of all the international, ethical guidelines,” Public Citizen warns Shalala. They “echo” the “notorious” Tuskegee syphilis study.

Nowhere in its 18-page document does Public Citizen acknowledge that babies’ lives may be saved by the low-AZT treatment of the women now in the studies. Neither does it acknowledge the ethical ramifications of its own efforts, which, if successful, will forfeit these lives. Rather, Public Citizen suggests, the African women are simply being used as guinea pigs to develop cheaper AZT regimens for Western women.

The researchers, in this view, are liars and cheaps, and killers to boot!

U.S. Standard Cited

Public Citizen objects to any study that provides less than the U.S. standard of care — Protocol 076 — to both the control mothers and those in the group treated with other regimens.

Public Citizen demands that the current trials be stopped — and wants the research scientists and their institutions, including CDC and NIH, investigated for possible criminal violation of the U.S. laws that protect research subjects.

If Public Citizen succeeds, it will, realistically, delay for months, if not years, studies that might reveal a rapidlyducible way to stop mother-to-child transmission of HIV. About 22% of babies born to these mothers will continue to die, as now.

Public Citizen acknowledges that cheaper, less-complex regimens would save lives, and says, “We are, therefore, not opposed to research that modifies . . . Protocol 076 in order to

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Researchers Reject Rap

Johns Hopkins University, in Baltimore, which conducts several of the studies attacked by the Ralph Nader/Sidney Wolfe activist group, Public Citizen, in Washington, has issued this rebuttal:

“The suggestion that all HIV-positive pregnant women should receive AZT in the regimen found to be effective in the U.S. is medically unsound and dangerously misguided. The cost of the drug alone in the Process 076 regimen . . . is estimated to be $800-$1,000 per woman.

“All ethical review groups that have reviewed the data from this study in the U.S. and in developing countries have determined that it is impractical and too expensive for developing countries, and that simpler interventions are needed. In order to adequately evaluate these interventions, controlled studies are necessary . . .

“If these trials are stopped, women in developing countries would be denied the benefits of these interventions. Moreover, if simpler interventions such as short course treatment are found to be effective, these studies will lead to practical, affordable interventions that can be used throughout the developing world. Not to conduct placebo controlled trials would be considered unethical, as implementation of unstudied regimens would expose women to potential risks without offering any known benefits.”
Charges May Delay Vital Research

identify a simpler, less expensive, similarly effective or more cost-effective intervention." Then, in what may be the pivotal sentence, the petition to Shalala continues:

"[W]e do object to studies in which . . . some or all women are only given placebos or regimens without support from randomized, placebo-controlled trials, and are not given effective prophylaxis."

This is circular reasoning with a dead-end result: Protocol 076 is the only regimen that meets the standards spelled out by Public Citizen in the sentence above. Hence, Public Citizen would require both the treatment arm and the control arm of all current and forthcoming studies to provide, minimally, Protocol 076. It is hard to see how such studies could be used to validate less-than-Protocol 076 regimens — which of course is precisely the challenge.

In an effort to clarify this contradiction, PROBE phoned the Public Citizen research associate who drafted (and signed) the petition, Peter Lurie, M.D. He is a young, South African-born family practitioner and health policy wonk who earned his medical degree at the Albert Einstein College of Medicine, in the Bronx, N.Y., and has been in clinical practice. He recently joined the Institute for Social Research, at the University of Michigan, Ann Arbor, where we reached him.

Redesign Sought

When PROBE asked Lurie what needed to be done to legitimize the studies, he said: "They need to be redesigned immediately so that some version of the AZT regimen proven effective in Protocol 076 is immediately provided to all women."

In other words, he confirmed, you can’t test the newer regimens directly.

Elsewhere in the telephone interview, and in some places in the petition to Shalala, Lurie and his co-signers — who include Public Citizen’s Health Research chief Sidney M. Wolfe, M.D., Yale internist George Silver, M.D., and Boston University bioethicist George J. Annas, J.D. — seem to suggest, contradictory, that if the controls were given Protocol 076, then the women in the treatment arm of the study might be given something less, provided — again circularly — that it was proven effective.

There is an unethical double-standard, Lurie insists, when you give the placebo to 100 women, because you are killing 14 babies. If you gave the same women AZT per Protocol 076, only seven would die.

Logic Challenged

This is Looking Glass logic: Without the current trials, or if they are stopped, the infection rate for pregnant women who do not get recruited stays at 22%. If the low-dose AZT regimens prove partly or wholly effective, some of the babies in the trial will be spared infection — and something vitally useful will have been learned for the millions like them to come. If, for example, an economical and practical AZT regimen is identified that will save half as many babies as Protocol 076, than 7 babies in the experimental group will have been saved who otherwise would become infected and die. And an additional 70,000 babies would be saved among the first million whose mothers get the new regimen.

Lurie and Public Citizen reject this logic, however. Whatever happens outside of science, in clinical practice in Africa, Lurie discounts as "a tragic circumstance that happens each and every day." But it does not bear directly on the ethical or moral legi-

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Co-signer Demurs

At least one signer of Public Citizen’s petition to Sec. Donna Shalala — seeking to curb the current AIDS clinical trials in the Third World — has reservations about the document’s hyperbole and incendiary rhetoric. But he stands firmly by the belief that these experiments are unethical.

This waver is bioethicist George J. Annas, J.D., professor of Health Law at Boston University (BU) and a regular contributor — on medical ethics — to the New England Journal of Medicine. He said in a phone interview that he and his BU colleague, Michael A. Grodin, M.D., a pediatrician, disagree strongly with Public Citizen’s equating the African studies with the Holocaust in the petition they both, nevertheless, signed. Annas said, however, that he and Grodin continue to believe the experiments are comparable to the Tuskegee study:

"The similarity is using people of color and poor people for purposes that are not their own."

He added:

"Michael Grodin and I wanted that [the Holocaust] taken out of the letter. . . . But Tuskegee might be the right analogy."

Annas also discounted the petition’s assertion that the studies are in criminal violation of U.S. law. He acknowledged that federal research regulations are not criminal statutes, and said "no criminal penalties" would be involved, even if Sec. Shalala agreed that the studies were flawed.

In a far-less-fevered piece that he and Grodin published in the Boston Globe (May 18), they write:

"The short-course regimen experiments are being conducted in Africa only because developed nations are unwilling to underwrite the distribution in Africa of proven therapies. Thus it is only the moral failure of wealthy countries that justifies the use of underdeveloped communities as experimental subjects."

Once you start giving a Third World mother or her baby AZT in a study, Annas added by phone, you are ethically bound to continue the drug — indefinitely.

# # #

One bioethicist whom we know, when told of Annas and Public Citizens’ position, remarked:

"They’re making the perfect the enemy of the good. That’s what they’re doing!"

We agree. — D.R.Z.
Cancer... continued from page 1

annually, according to official U.S. Federal Trade Commission (FTC) documents.
CTCA has since added a third center, in Virginia, according to a recent news report.

Agency Takes Action

In 1992, the FTC, which has regulatory jurisdiction over medical advertising and protects consumers from false claims, began an investigation of CTCA's ads and sales brochures. This led to CTCA's signing a consent agreement to cease and desist from several claims the agency judged to be false, unsubstantiated, or deceptive.

The main thrust of FTC's case, according to internal memoranda, was that "in the marketing of their services [CTCA] have misrepresented their survival rates, made atypical testimonial claims [that are] accompanied by either inadequate disclaimers or, in some instances, none at all. [A]nd [they] failed to possess adequate substantiation for claims regarding the efficacy of certain of the 'innovative procedures' they promoted.

Last year, the FTC released the text of the consent agreement and its order binding CTCA to it, both couched in legal language. The agency also released a brief, tightly-written legal analysis of its action. These documents contain few data that could help the average person decide whether to seek treatment from CTCA or other "holistic" cancer care providers, who purport to go beyond or offer alternatives to the standard modes of surgery, radiation and drugs.

Claims Are Banned

The FTC banned some of CTCA's unsubstantiated claims, and ruled that any future claims will have to be based on valid and objective scientific data. The agency also noted that, short of signing up for CTCA treatments, and perhaps spending thousands of dollars for them, consumers may have no way to evaluate some of the CTCA claims for the efficacy of its treatments. Even under threat of federal action, CTCA declined to back up some key claims, particularly that more of its patients live longer, compared to those treated elsewhere.

To provide consumers a more discursive description of FTC's charges, CTCA's responses, and the steps leading to their settlement, PROBE requested relevant FTC documents under the Freedom of Information Act (FOIA). Some were sent. PROBE also received a copy of FTC's original complaint against CTCA and agency memoranda that elucidate and explicate its actions.

We hope this report will help cancer patients and their families and friends assess their treatment options. — D.R.Z.

How Ads Bring Business

This description of CTCA's patient recruitment, quoted in an FTC document, is from a Page 1 news story in the *Dallas Morning News* (June 21, '92): "Prospective CTCA patients are diagnosed with cancer, often at a small rural hospital. They go through standard initial treatment — radiation, chemotherapy, surgery... But the cancer remains and a doctor delivers what patients hear as a death sentence. Casting about for an alternative, they spot an ad. Perhaps it is on CNN or in *Parade Magazine, Prevention, People, Reader's Digest* or one of the other publications CTCA uses. And they call the 1-800 number.

CTCA telemarketers determine the kind of cancer and the amount of private insurance. If coverage is adequate, a patient is accepted. CTCA then pays to fly the individual and a guest to its nearest hospital. The patient's subsequent travel costs are also picked up by CTCA. Many patients recount how they were met at the airport by a limousine and taken to the hospital. They generally faced a series of blood tests, including immune and nutritional assays. CT scans were usually done from the head to the pelvis. Much of the time, a bone scan was ordered.

Most patients receive chemotherapy. The tests and medication take about a week in-patient hospital time. The patient usually returns about once a month for another week of tests and treatment. The visits can continue for months or years.

Claims... continued from page 1

survival rates ranked among the highest documented." "You Can Best Cancer. I'm Living Proof..." This is the headline of a CTCA ad.

These ads depict real patients. They "purport to portray real patients of CTCA centers who have achieved long-term remission of their cancers," FTC staff says. "The implication of these ads is that the patients portrayed, having successfully achieved long-term remission... represent the typical and ordinary experience of CTCA cancer patients."

Patients Are Real

CTCA satisfied FTC that these are or were real patients. CTCA said that, when last checked, in 1993, all were still in remission.

FTC asked for documentation that these case histories represent the "typical and ordinary experience" of CTCA's patients. But, CTCA "did not provide any documentation."

Their lawyers said, rather, that FTC's guidelines for endorsements and testimonials should not be applied to cancer therapies where, typically, patients have been unsuccessful with traditional methods, and have become "sophisticated" by their experiences (and thus, apparently, know how to read between the lines — D.Z.). What is more, CTCA argued, the ads also contained disclaimers, in small type, such as "the effectiveness of any treatment program depends upon a variety of factors and..." continued on page 8
Deceptions Persisted, Federal Agency Says

While the FTC was investigating CTCA, the company ran a series of prominently-placed ads in the New Yorker. The ads stressed CTCA’s "holistic" approach to cancer therapy.

One of these ads, published on March 13, 1995, was headlined:

"Blanche Taylor Found A New Life After Cancer."

The text, as cited in a memo from FTC's division of service industry practices, indicates that Taylor's breast cancer was diagnosed in 1986. She "refused to accept the traditional treatment approach — surgery, chemotherapy, and radiation . . . . Instead, she searched for a treatment program which supported traditional therapies with nutrition, emotional and spiritual support, and lots of tender loving care."

According to the ad, Taylor is a cancer survivor because of CTCA's treatment plan, "which was both effective and acceptable to [her]." But CTCA told FTC that besides the adjunctive therapies listed in the ad, Taylor "also was treated by mastectomy, radiation therapy, and chemotherapy" — precisely the treatments she earlier had explicitly rejected.

FTC was displeased that CTCA "continues" to "draw in patients" with "testimonial claims," Bernstein writes. But "we have not included them in the [FTC] complaint [against CTCA] in order to avoid raising obstacles to an already drawn out settlement process."

Such testimonials she added will be "fully covered" by FTC's order to cease and desist, which went into effect last year.

CTCA Owner Not Cited

Behind a congeries of corporations identified in FTC documents as Cancer Treatment Centers of America (CTCA), is a single principal owner, the agency says. A December 18, 1995 memo to the Trade Commission from Walter C. Gross, the senior staff attorney in the agency's Division of Service Industry Practices, says, in a footnote:

"Richard J. Stephenson is chairman of the board of each of the corporate respondents, and the ultimate owner, through stock ownership in the respondent holding company for the Illinois and Oklahoma hospitals. By profession, Stephenson is a lawyer and a venture capitalist."

The Gross memo says FTC's staff "explored the possibility of naming Stephenson as a respondent" in the case:

"[I]n negotiating this possibility (against strong objection), we determined this should not be a condition of the FTC's settlement" with CTCA.

In an earlier, November 6, 1995 memo to the Commissioners, Gross explained:

"Because of his positions of authority and ownership, we believed that we had a colorable argument for naming him individually. His absence as a party to this consent agreement is a result of consent negotiations. Dropping Stephenson as a named respondent in this matter permitted us to reach agreement with respondents."

In the subsequent, December memo, Gross explains that his division's decision not to name Stephenson reflected CTCA lawyers' explanation that "marketing decisions are not overseen by Stephenson, nor are the medical/scientific decisions."

At least one of FTC's charges against CTCA dates back to 1991, before the previous owners, Bob Lane and Randall Pittman, left, according to a report by Ken Garber, in last month's issue of the Ann Arbor Observer.

CTCA Vigorously Fought FTC's Probe

The CTCA fought hard to keep the FTC from censuring its ads and promotional practices.

Early in the investigation, CTCA lawyers said FTC's rules and regulations with regard to endorsement and testimonial ads and promotions should not be applied to claims for the cancer treatment. The reason, they explained, was that the patients they attract with their ads have already experienced treatment failures, and so are "sophisticated" about claims made for other cancer treatments and cures.

The CTCA lawyers also argued that disclaimers on the ads — such as "The effectiveness of any treatment program depends upon a variety of factors and differs from patient to patient" — adequately informed prospective patients of what they might expect from treatment.

Argument Pressed

The FTC lawyers rejected these and other CTCA arguments. They said that the "target audience" for the ads are "a particularly vulnerable class of consumers, desperate for cures," who thus need accurate information on what the treatments provide. The settlement process was long and "drawn out," FTC attorney Walter C. Gross wrote in a memo to the Commissioners in November, 1995.

"Respondents have very reluctantly signed the consent." Jodie Bernstein, director of FTC's Bureau of Consumer Protection wrote in a memo to the commissioners several months later. She said CTCA had argued that "as a policy matter, the Commission should not proceed against advertising that a marketer had voluntarily discontinued before receipt of a Commission inquiry."

The FTC lawyers disagreed. Nevertheless, Bernstein writes, CTCA's lawyers met with her and with her predecessor to press this claim.

Document Signed

When these arguments failed, CTCA signed the proposed consent agreement in September 1995, and it was accepted by FTC's staff. The consent agreement provides for a settlement of charges against CTCA, and it prohibits the company from making certain promotional claims in the future.

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Claims... continued from preceding page

differs from patient to patient.”

The FTC rejected those arguments, saying that the “atypical” testimonials in the ads fail to “reflect the typical or ordinary experience of members of the public” — in this case terminally ill and hence “particularly vulnerable... consumers, desperate for cures” — who use the advertised product or service.

“We believe,” the agency lawyers continue, that CTCA “realize that the actual percentage of successful remissions in CTCA patients... cannot reasonably be considered ‘significant’” — the FTC standard — “under anyone’s standards.”

The FTC charged CTCA with making unsubstantiated claims for efficacy. A discontinued brochure said:

The outlook has previously been bleak for people with certain forms of cancer, which resisted conventional types of treatment. Today, as a result of several treatments we were instrumental in pioneering, these cancers are beginning to yield.

Whole body hyperthermia [WBH] is one... An approved medical procedure that raises the body’s temperature to kill cancer cells without harming the normal cells... it is the product of years of meticulous research.

CTCA “has not provided documentation that substantiates this claim,” the FTC staff reported. In fact, WBH had long been studied, is considered a “toxic” method, and has been “abandoned” by mainstream medicine for more than a decade, the staff said, based on NCI consultants and published scientific sources. Alternativists, however, do use WBH.

FTC said CTCA did produce investigational protocols from its own doctors discussing WBH’s “theoretical” benefit. Asked to describe its own experience with WBH, the CTCA admitted that it was only marginally effective, and yielded only “occasional dramatic anti-tumor response”; the median remission was less than one year.

CTCA Says Claims Dropped

CTCA complained that it had dropped its WBH claims in 1992. But FTC said that CTCA’s own doctors had published their findings on hyperthermia’s low efficacy in 1990 — yet the company continued to promote WBH for two more years.

“CTCA, therefore, possessed data — which they should have considered reliable since it was their own — that called into question its claim about the efficacy of WBH at least two years before it effectively withdrew the claim,” the FTC says. “Thus, it is unnecessary, we believe, to rely solely on the prevailing opinion of the mainstream medical community that WBH is only marginally efficacious in the treatment of cancer in humans... [CTCA’s] own reports confirm that.”

The FTC concluded that the hyperthermia claims were false and misleading. It said that some of the CTCA claims discussed above “are very serious and harmful to consumers.” It said “there is inadequate substantiation for the efficacy of any of CTCA’s unique alternative treatments,” and, in its view: “It... is unlikely that CTCA’s program offers any measurable success over [other] treatments.”

CTCA Responds

We faxed our articles on CTCA to the company, and asked them to correct any errors of fact, and comment on the report if they wished. CTCA’s director of marketing, Constance A. Mulford, replied in a three-page, single-spaced letter, which stressed that CTCA provides a “comprehensive array” of standard and adjunctive treatment services. Staff members are well-qualified, her letter said, and the treatment units are all locally and nationally accredited, one of them “with commendation” by the Joint Commission of Accreditation of Healthcare Organizations.

The part of Mulford’s letter that specifically pertains to our report is as follows:

“CTCA... does... not ‘gull’ patients. [This] statement in the draft headline [is] false and misleading. [It is] neither supported by the substance of your articles, nor by the facts.

“Your articles appear to confuse CTCA’s holistic, comprehensive approach, which combines traditional medical and surgical services and therapies with other forms of support (such as nutritional and psycho-social), with the approach of providers that offer only traditional medical and surgical services. The support services provided by CTCA are adjunctive services and do not take the place of traditional medical services.

“In addition, we note that your articles appear to confuse the FTC’s action in this case with the opinions expressed by certain members of the FTC staff. The principal action the FTC itself took in this matter was to approve a settlement agreement (which included a consent order) with CTCA relating to advertising. The FTC itself did not opine on any of the evidence or arguments in this case and did not (and has no jurisdiction over) the medical services provided by CTCA. The memoranda that you purport to cite in the article were apparently written by FTC staff attorneys.

“Please note that in agreeing to put the matter behind it, CTCA did not admit to any liability under the FTC Act.

“Moreover, the consent order addressed only the accuracy of certain advertising claims about the quality of CTCA’s patient care. The FTC specifically indicated in its March 13, 1996 official press release that ‘no inference should be drawn about the quality of care provided by (CTCA) at (its) hospitals.’ No regulatory body with jurisdiction over medical practices has questioned the quality of care provided to patients treated at CTCA.”

Benefits Cited

“CTCA works purposefully to empower each patient to actively participate in decisions about his or her treatment by providing unbiased education about treatment options...

“CTCA operates high quality in-patient and out-patient oncology programs in hospitals... The [ir] accreditations... attest to the high quality and standards maintained by these hospitals... [All] physicians associated with CTCA are licensed in the states in which they practice, and the majority of them are board certified....”

— CTCA to PROBE, June 17, '97
Fought... continued from page 7
the Federal Trade Commissioners last year. In the agreement, CTCA promises to "cease and desist" from claiming "directly or by implication" any "survivorship rates or cure rates for cancer patients" in its own or other facilities unless: they possess and rely upon "competent and reliable scientific evidence" that substantiates the claims.

The Commission defines competent and reliable scientific evidence as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."

Promises Are Made
The CTCA similarly agrees not to misrepresent the benefits of any of its methods or falsely claim independent acceptance or endorsement of any of its methods. In its ads and other promotions, CTCA agreed it would prominently disclose what the "generally expected" results of any of its treatments would be, and that when presenting unusually good results to state "prominently and in close proximity" to the individual patient's endorsement that "consumers should not expect to experience similar results."

These agreements were incorporated into an FTC order to CTCA to cease and desist from the previous practices. The order remains in effect until the year 2016.

Charges... continued from page 5

imacy of the researchers' work — which, he says, must be judged by separate, higher standards based on the standard of care in the sponsoring country, such as the U.S.

Racism Alleged
Public Citizen's efforts to equate the Tuskegee Study and other past racist practices seems to us to be gratuitous rabble-rousing. They are especially inflammatory since CDC, a lead agency in the African trials, is a part of the U.S. Public Health Service, which ran the Tuskegee study. But the studies aren't comparable:

No therapeutic intervention was tested on the Tuskegee volunteers. The current AZT trials are testing interventions designed to help the current research subjects as well as future patients.

Link Denied
Public Citizen's effort to link the African AZT studies to the Holocaust, as violations of the Nuremberg Code, seems similarly cynical — and far-fetched. What is being done to — and for — the women in the AZT studies is in no way comparable to what the Germans did to mentally defective persons or Jews or anyone else in their concentration camp experiments. It is not comparable, either, to what the Japanese did in their freezing, poisoning, and live-dissection "experiments" on Chinese prisoners after the rape of Nanking.

It's an odious comparison.

Conditions Are Different
Substantively, if the CDC researchers and the others had deliberately infected the African AZT subjects with HIV, or had made them pregnant, the studies would of course be unethical. But these women became infected and became pregnant without medical intervention. Public Citizen claims it is unethical to try to help them in any way — unless you give them the very best that American medicine has to offer.

The assertion that a researcher must provide the entire American standard of care while testing a derivative of one piece of it abroad is in itself absurd! The obstetric standard of care in the U.S. includes ICUs, and a wide range of costly methods that are not available in the Third World, certainly not out in the bush.

Must the standard of care in America be provided whenever one tests a drug or other medical intervention in the Third World?

Public Citizen's Lurie hemmed and hawed when we put this question to him, and acknowledged that, for example, researchers would not need to set up a coronary care unit in order to test a heart pill on African subjects, since the cost would be "enormous." But providing AZT for all women in the studies is "relatively straightforward," he insisted.

Figuring that the additional AZT might, conservatively, cost $1,000 to buy and deliver, the cost for the 6,783 women who Public Citizen charges are being under-treated — or who are not being treated, since they are getting placebos — would be $6.7 million.

At our press time, Sec. Shalala had not responded to the Public Citizen petition. We think she'll reject it. But, suppose she agrees with it, and pulls the plug on the current studies in order to assess and redesign them.

Very shortly, individual women who would have been in the treatment arms of the studies will begin to deliver their babies without having received any AZT or other effective anti-HIV medication. Most of the babies, who might have been HIV-negative if the clinical trials had continued, will be HIV-positive. They will die.

PROBE asked Peter Lurie if he and Public Citizen will be responsible for these deaths. He said: "No."

We beg to differ.

Correction

The New York City blood donors who have been found to carry signs of infection with HTLV-1 virus are not all men, as we reported last month. The donors included men and women, hematologist Dorothea Zucker-Franklin, M.D. of New York University, reported in Lancet.
Plucked from the Internet:
Cleaner Polishes Off Patients

The following dispatch, allegedly from the Cape Times, in Capetown last June 13, showed up on the Internet, with the notation: “This is a real article.” — Ed.

“For several months, our nurses have been baffled to find a dead patient in the same bed every Friday morning,” a spokeswoman for the Pelonomi Hospital (Free State, South Africa) told reporters. “There was no apparent cause for any of the deaths, and extensive checks on the air conditioning system, and a search for possible bacterial infection, failed to reveal any clues.

“However, further inquiries have now revealed the cause of these deaths: It seems that every Friday morning a cleaner would enter the ward, remove the plug that powered the patient’s life support system, plug her floor polisher into the vacant socket, then go about her business. When she had finished her chores, she would plug the life support machine back in and leave, unaware that the patient was now dead.

“We are sorry, and have sent a strong letter to the cleaner in question. Further, the Free State Health and Welfare Department is arranging for an electrician to fit an extra socket, so there should be no repetition of this incident. The enquiry is now closed.”

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