Fisher Vindicated; Pitt and NCI Pay: He Gets Millions – Plus Apologies

A settlement has been reached between Pittsburgh breast cancer researcher Bernard Fisher, M.D., and the institutions that tried to destroy his career and his reputation three years ago: the University of Pittsburgh, where he conducted ground-breaking cancer studies over more than three decades, and the National Cancer Institute (NCI), which had supported these studies.

Pitt fired Fisher as head of the international breast cancer research consortium that he ran. NCI had accused him of scientific misconduct because one research associate submitted false data — which Fisher, properly, had immediately reported to NCI.

In the settlement, late in August, he won apologies and cash: $2.75 million from Pitt, $300,000 from NCI.

The settlement was reached a few days before a lawsuit Fisher had filed against Pitt and NCI was set to go to trial before a federal judge in Pittsburgh. Fisher charged the defendants had deprived him of his constitutional right to due process, and violated his right of assembly by preventing him from freely associating with his research colleagues in the consortium, the National Surgical Adjuvant Breast and Bowel Project (NSABP). He also charged that NCI and its overseeing agencies — the National Institutes of Health, The Public Health Service’s Office of Research Integrity, and the Department of Health and Human Services violated his right to free speech by censoring citations for his publications in federally-run medical databases.

Pitt said in a statement released as part of the settlement:

“[A]t no time was Dr. Fisher found to have engaged in any scientific or ethical misconduct concerning any of his work.”

NCI admitted no wrongdoing, but issued a statement that says:

“Fisher has been a dominant force in the study of breast cancer for the past 40 years . . . .”

Newspaper Applauds

The Pittsburgh Post-Gazette, in an editorial “Welcome Apology” (Aug. 30), noted that Fisher “had spearheaded

All Top Scientists Are Now Cleared

Pittsburgh breast researcher Bernard Fisher, M.D. is the last high-profile scientist pilloried in the press by Chicago Tribune reporter John Crewdson, and in Congress by Congressman John D. Dingell, to be fully vindicated.

“This closes the chapter,” retrovirologist Robert Gallo, M.D., an earlier victim, said last month in Baltimore. Gallo and his associate, Mikulas Popovic, M.D., were cleared of all misconduct charges after years of hounding by Dingell and the agencies whose budgets he controlled. In the Popovic case, administrative judges said of the Office of Research Integrity (ORI), which brought the case:

“One might anticipate that for all this evidence, after all the sound and fury, there would be at least a residue of palpable wrongdoing. That is not the case.”

No Work Available

Because of the charges, Popovic, an immigrant, was unable to find full-time scientific work in the U.S., and he returned to Europe. After the judges dismissed the Popovic case, the ORI dropped its case against Gallo.

The Dingell-driven attacks on Nobelist David Baltimore, and his foreign-born MIT research associate Thereza Imanishi-Kari took a decade — and a cruel emotional toll — before they, too, were dropped.

A Dingell probe cost Stanford University president Donald Kennedy his job. Only later was Kennedy found innocent of any wrongdoing.

A Cleveland biochemist, Rameshwar Sharma, Ph.D., was similarly accused of criminal misconduct by Dingell, driving him to consider suicide, before federal judges vindicated him three years later. His “misconduct” turned out to have been a single, obvious and unimportant typographical error, our colleague Jock continued on page 6
Our critique last month of the *Ladies’ Home Journal* piece on lung cancer did not sit well with its author, the medical writer Sarah Wernick, of Boston. She is a member of the American Society of Journalists and Authors, as we are. Wernick has been telling our colleagues — and us — that we are dishonest, inaccurate, and unworthy of respect. She nevertheless sent PROBE a letter to the editor, which we are delighted to publish, below, followed by a few comments of our own in response.

(We sent last month’s piece to Myrna Blyth, editor-in-chief of the *Journal*, asking for comment. She has not replied.)

Here is Wernick’s letter:

In claiming that this article “bent over backwards to accommodate LHJ’s tobacco advertisers,” David Zimmerman has accused me of serious professional misconduct.

In fact, I did not downright the role of cigarettes in my article, nor was I asked to do so by the magazine. Their letter assigning the article — as Mr. Zimmerman knew — specifically directed me to feature smoking. Scrutinizing editorial changes as a whole, which is the only fair and honest way to do it, there’s no evidence that they were motivated by a desire to downplay the role of cigarettes.

Mr. Zimmerman points to the fact that the article described an atypical lung cancer patient, a non-smoking woman in her 30’s. As I explained to him, the editors told me they wanted to feature a young non-smoker because most of their readers are young non-smokers themselves and would be intrigued by the case’s mystery. One could argue with the merits of using atypical patients for this reason, but the editors do so often, not just when tobacco is involved. LHJ’s June 1996 article about colorectal cancer (which I was told to use as a model for mine) led with a woman in her 30’s, yet more than 90% of sufferers are over age 50. A May 1996 piece on cervical cancer featured a woman who had died of the disease in her 20’s, despite having had several negative Pap tests — another atypically young patient who followed all the standard preventive health advice and still got cancer.

In a sidebar on prevention, I quoted a nutritionist who recommends that smokers eat a carrot a day. Mr. Zimmerman took me to task for this suggestion — which is amply supported by epidemiological data on diet and health. He noted that the editors cut part of the quote, a warning that carrots don’t counterbalance smoking. However, the editors also added material to the same prevention sidebar: anti-smoking statistics from the American Lung Association. The opening quote, which Mr. Zimmerman didn’t mention, was: “It’s incredibly important for adults to stop smoking and for parents to get their children not to start.”

Over the past four years I’ve approached every major women’s magazine with a proposal to write about lung cancer. All the others turned me down. If *Ladies’ Home Journal* had wanted to cater to tobacco advertisers, they could have done the same. But they didn’t. — Sarah Wernick

We reported very carefully, based on phone talks and faxes from Wernick, that her LHJ assignment directed her to feature a young, non-smoking woman.

This stipulation came from the *Journal*, as we made clear, and the only possible reason for it, in our view, is to accommodate LHJ’s tobacco advertisers. We did not criticize Wernick for accepting the assignment under this condition.

We continue to believe it is disingenuous, at best, to focus a piece on the epidemic of lung cancer in women on one woman who never smoked. It’s like featuring a celibate nun in a piece on the AIDS epidemic.

**Clues Missing**

The stuff about readers being “intrigued” by the “mystery” of the case would be more credible if Wernick had provided the key clue of what kind of breast cancer her subject is suffering. She didn’t. Also, focusing on a woman who presumably had done all the right things, and got cancer anyway, while true in a minority of cases, can only discourage women in the far larger group who could make a difference — and save their own lives — by stopping smoking.

Wernick does tell readers to stop smoking, but never in a simple and direct way: Stop smoking. She rather couches this advice in sentences of tacit understanding, such as the one she quotes in her letter, or “Cigarettes, of course, are the chief culprit.”

**Statement Challenged**

This wording reminded us of recent cigarette company statements: For years, they claimed their product didn’t cause cancer; then, after they reached a tentative settlement with the States attorneys general, in August, they began saying, “As everybody knows, cigarettes ....”

We don’t think a writer who is not a scientist can or should make health recommendations like *A carrot a day chases cancer away*, based on unpublished data. Period.

While Wernick’s letter, and the article, do talk about prevention, it is noteworthy that they offer no specific advice on how to stop smoking, even though, we’re fairly certain, some LHJ advertisers sell products that may help.

More broadly, we’re pleased that Wernick is angry, though sorry her feelings are hurt. As we indicated last month, medical
Experts Hail Gulf Ills Finding, But More Research Is Needed

Infectious disease specialists and tropical medicine experts who study and treat leishmaniasis (say leash-man-EYE-a-sis) are impressed but cautious about findings on a new test for the disease that is being developed on the West Coast, as reported exclusively in PROBE last month.

“This represents the best evidence that these people [Gulf vets] might really have been infected with Leishmaniasis tropica,” infectious disease specialist Franklin Neva, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID) told PROBE by phone late last month. “If the experiment in Portland, Ore., can be confirmed," Neva added, "this is one of the best clues that has come along.”

Results ‘Impressive’

Immunologist David Sacks, Ph.D., his NIAID colleague agreed: “I'd like to see the actual data, and at this point it's a very small study. But: It's very impressive!”

In the study, conducted at the Portland, Ore., Veterans Affairs (VA) Medical Center and at Corixa, Inc., a Seattle biotech company, sera from 100 Gulf vets were tested blindly, using an immunologic assay developed by Corixa based on a protein from the parasite Leishmaniasis tropica, found around the Persian Gulf.

Ten out of 102 specimens reacted to the L. tropica, indicating the individuals had previously been infected by that organism. Of the 10, eight had current or past symptoms of Gulf War syndrome. Two other veterans with known clinical cases of leishmaniasis also were positive in the Corixa test, as were a group of Turkish soldiers suffering typical L. tropica sores.

By contrast, serum samples from people who are believed not to have served in the Gulf all turned out negative — they did not respond to the L. tropica protein in the test.

More Work Needed

Experts contacted by PROBE agreed with the Portland VA researcher, toxicologist Peter Spencer, Ph.D., who reported the test to colleagues earlier this year, that more work is needed to confirm the test’s validity and usefulness. Infectious disease specialist Sherwood L. Gorbach, M.D., of Tufts, in Boston, noted that Spencer and his colleagues have not reported how many, if any, of the 100 vets have clinical manifestations of Gulf War syndrome, but did show up positive in the test. NIAID immunologist David Sacks concurs.

“I wonder how many he [Spencer] missed,” Sacks said. “I just wonder, did he pick out almost everyone who had the syndrome?”

At Corixa, in Seattle, test-developer Steven G. Reed, Ph.D., an immunologist, thinks L. tropica may be responsible for some but not all Gulf syndrome cases. “It's obvious some people were infected over there,” he told PROBE early this month by phone. “Whether it’s a significant cause, we don’t know. But I have no doubt that it's not the main cause.”

The reason, he explained, is that many Gulf vets’ symptoms differ from those of leishmaniasis.

Could the Corixa test be identifying leishmaniasis that service personnel picked up in other places, such as Panama, where many had trained — and where there are different forms of the disease? Reed thinks not.

“There doesn’t seem to be any cross-reactivity” between L. tropica and other Leishmania, he said.

A Center for Disease Control (CDC) expert is not so sure. Infectious Disease epidemiologist William Reeves, M.D., who attended the experts’ meeting on the Corixa test findings in Portland, in August, said the test is “promising," but declined to draw any conclusions from the results because, he said, “I think they are nonspecific.” Gulf warriors could have become infected with leishmanial organisms on assignments elsewhere in the tropics, he said, and thus show up as positive in the Corixa assay.

Tests Compared

Reeves is honchoing CDC’s long-awaited Pennsylvania National Guard study, which was published in part, in preliminary form in CDC’s Morbidity and Mortality Weekly Report (MMWR), on June 18, 1995. It confirms Katherine Leisure’s earlier, but unpublished finding that many vets are ill, with physical findings that are not attributable to stress, as the Department of Defense had suggested (PROBE, Jan.).

Reeves told PROBE by phone that the CDC study participants have been tested with both the Corixa test and an earlier, indirect fluorescent antibody test for L. tropica. The findings do not correlate, he said.

Some of the Gulf vets react to the fluorescent antibody test; a larger percentage respond to the Corixa test. But very few who respond to one of the two tests respond to the other. There is little cross-reactivity between the two tests, he said.

One reason, he suggested, may be the test substrates: The fluorescent antibody test is based on proteins from the free-swimming, or promastigotal, stage of the L. tropica life cycle. The Corixa test substrate is a 45-based pair strand out for Leishmanial drugs; only a small amount of their pre-treatment sera is available. He said he favors re-contacting these individuals to ask for more blood, and also favors careful surveillance for additional cases of visceral leishmaniasis — which thus far have not been forthcoming.
Gulf Veterans’ Lesions — Are They Leishmaniasis?

Sore on nasal septum (photo left, arrow) and leg ulcer (center) were photographed by infectious disease specialist Katherine Murray Leisure, M.D., on military veterans whom she examined at the VA Medical Center in Lebanon, Pa., after the Gulf War. Man with nasal sore is a Navy diver who did not arrive in the Gulf until July, ’91, four months after hostilities ended; he was never near the war front. Man with leg ulcer worked in desert for only one month, October 1990, before Desert Storm.

Vet with scar (photo right) was plagued by persistent skin eruptions — “Saddam’s pox” — and had low platelet counts. Scar is from surgical removal of his spleen. He arrived in Gulf on Jan. 1, 1991, worked amid camel herds, and became ill three months later.

Leisure classifies these cases clinically as MIRDS, mucocutaneous-intestinal-rheumatic desert syndrome. Her hypothesis, which has not been confirmed, is that they are caused by parasite *Leishmania tropica* that is transmitted to humans by a sandfly (drawing, top). Free-swimming form of this parasite, which is 2 microns long and has whip-like flagella for locomotion, is called a promastigote (below sandfly). It penetrates white cells (macrophages) or other cells, where it is transformed into a life stage called an amastigote (black dots in cell in front of fly). The amastigotes reproduce in human cells. Sandflies ingest them while biting humans or other hosts. The leishmania change again into promastigotes; the cycle begins anew.

Essay: On Ockham’s Razor and Gulf Ills

The analytic instrument we feel most comfortable wielding, journalistically, in exploring the cause of Gulf Syndrome is Ockham’s Razor. It is named for, but apparently was not quite explicitly stated in the writings of English philosopher William of Ockham (circa 1300-1349).

Also called the Principle of Parsimony, it states that: “Entities are not to be multiplied beyond necessity.”

The meaning, as explained in philosophical dictionaries, is that the razor cuts away useless or gratuitous ideas in explaining a phenomenon. One should accept, rather, the simplest hypothesis that can explain the data.

In the elucidation of diseases and their causes, the less that is known about an illness at the onset, the more possible causes it has. Think about all of the “causes” adduced fifteen years ago for AIDS! They include dope, sensation-enhancing drugs (poppers), etc. In the end, after scientific investigation, only one essential cause remains: HIV.

No virus, then no disease, no matter what else is happening.

By the same token, Gulf War syndrome has been attributed to a variety of causes, including, according to the Presidential Advisory Committee, these top 10 candidates: 1. Biological warfare agents 2. Chemical warfare agents 3. Depleted uranium in shells, armor 4. Infectious diseases 5. Oil-well fires 6. Pesticides 7. Petroleum products 8. Stress 9. Pyridostigmine bromide as an antidote to poison gas 10. Vaccines

Several of these putative causes, such as oil-well fires, can be eliminated if, as continued on page 6
Why’s Described

Two questions about Gulf War illness beg answers:
• Why is it important?
• Why might the Pentagon and the Administration “cover up” the putative causes, as ex-VA physician Katherine Murray Leisure, M.D., of Hershey, Pa., and ex-CIA analyst Patrick Eddington, author of Gassed in the Gulf (Washington: Insignia) allege (PROBE, Sept.)? Here are their answers:

To explain the illness’s importance, Leisure and Eddington cite Abraham Lincoln’s Second Inaugural Address (March 4, 1865):
“Let us care for him who shall have borne the battle.”

Why Hide It?
In an account from his book of an interview with his CIA legal officer, analyst Eddington quotes him as asking:
“If [your charges] are true, why are [Sec. of Defense Perry and Gen. Shalikashvili] lying? . . . What do they have to gain?”

Eddington replies:
It’s not what they have to gain, it’s what they have to lose if the truth comes out . . . The plain fact of the matter is, that contrary to [Gen. Colin] Powell’s statements, we were in no position to deal with a real chemical threat on the battlefield.

Also:
“There’s the cost of dealing with all these sick vets.” The “compensation” would unbalance the budget.

The Bush administration covered up, Eddington charges, because Iraq chemical weapons — possibly purchased in part in Germany. This ordnance appears to have been sent to Iraq by Reagan-Bush to support Saddam Hussein’s war with Iran. Eddington says:
“The U.S. . . . had not only violated its own ban on lethal assistance to Iraq, it had violated its own nonproliferation policy as well by providing Iraq with the means to deliver chemical agents against Iranians and, later, our own troops.”

Compensation Is An Issue
The Clinton administration, Eddington adds, is “too cheap to pay” the vets compensation for their ills, and “too cynical to care.”

More broadly, the DoD has represented the overwhelming allied victory in the 100-hour Kuwaiti war as redeeming the military’s reputation from the Vietnam debacle and the long years of wrangling that followed over Agent Orange. To admit that they goofed again, in the Gulf, would be to tarnish this barely-recovered credibility.

By covering up, on the other hand — as they appear to be doing — the military is alienating a large group of heretofore loyal and patriotic Americans. Their anti-DoD and anti-governmental anger resonates — dangerously — with the wider anti-federal rage simmering in the hinterland.

Infectious Disease 101:
Leishmaniasis Is Little Known But Widespread

It’s not a household name. But leishmaniasis, a complex and bewildering group of illnesses, experts say, occurs in wide areas around the globe. Infected people and their dogs — which also carry the disease — continue to extend its range.

The symptoms vary, from a single, hard nodule in the skin to severe internal damage, particularly to the liver — which can be fatal. The cause is tiny microorganisms called Leishmania. They are transmitted between mammals, including man, by sandflies. The sandflies tend to bite and the microorganisms tend to live in non-human mammals, particularly dogs and gerbils.

The only effective preventive measures thus far are to avoid infected mammals, to avoid sandfly bites by using insect repellents; and, generally, stay away from sand and dirt in affected areas of the five continents where leishmaniasis presently occurs (only Australia is spared).

Parasites Metamorphose

Months to years may pass between the time the tiny, elongated protozoans enter the human body from sandfly saliva and the onset of symptoms. The parasites, meanwhile, have changed into roundish organisms that live inside the victims’ white blood cells, liver cells, and some other target cells and tissues.

The symptoms are indistinct, so that the diagnosis has been hard to make on a clinical basis. This may be one reason why it has taken so long to identify leishmaniasis as a cause of Gulf War syndrome.

At present, the diagnosis requires cultivating cells obtained from skin or internal biopsies until the parasites multiply and can be found by microscopic examination of the cultured cells. This has been done for only a few dozen Gulf vets — which is why a simpler diagnostic method, a blood test, for example, has been avidly sought. With such a test available, it would be possible to rapidly and inexpensively determine which of the 700,000 sick and well Gulf vets and their immediate family members were or are infected.

CDC Supplies Drug
Current drug therapies aren’t terrific. But they’re not so bad, either, according to infectious disease specialists at the National Institutes of Health and others who use them.

Antimonial drugs, like those that long were mainstays of syphilis treatment, are the main therapeutics; sodium stibogluconate (Pentostam, Wellcome) is available in the U.S. from the CDC, in Atlanta. Pentamidine, allopurinol and amphotericin continued on page 8
Scientists... continued from page 1
Friedly reports (The Hill, Sept. 3).

Bureaucracy Remains
The witch-hunt is over. But the bureaucratic engines of torment — particularly the shamed and failed Office of Research Integrity — remain in place. Dingell apparently is unrepentant. "To date, I have never received a letter of apology from him," Sharma says.

No accounting has yet been made about why and how this egregious violation of rights, affecting some of America's most productive researchers, could have occurred. The spillover effects on other scientists and on the public's respect and regard for science have yet to be measured.

There has been no recognition that Dingell created the worst anti-intellectual witch-hunt since Senator McCarthy and the Red Scare of the '50s. No safeguards are yet in place to insure that it won't happen again.

Fisher...
continued from page 1

ground-breaking research into breast cancer that gave millions of women hope that the less-disfiguring lumpectomy could be as effective a treatment as radical mastectomies in many cases."

Fisher told reporters:
"This not only restores my reputation, but reaffirms the quality of my research."

Fisher's troubles stemmed mostly from sensationalized accusations contained in articles by investigative writer John Crewdson of the Chicago Tribune, recycled by the New York Times, that were picked up by congressional committee chairman John D. Dingell (D-Mich.). He and his staff brutalized and humiliated Fisher in hearings in 1994.

Rights Violated
What was "so revolting" and anti-democratic about this experience, Fisher told reporter Jock Friedly last month, was the violation of his constitutional rights.
"I did not have due process," he said (The Hill, Sept. 3). "What due process I did have was adversarial."
Friedly called Dingell's office for comment on the settlement. He says his calls were not returned.

Throughout his ordeal, Fisher, now 79, has made it clear that he was not prepared to take a pat on the back and a gold watch, and fade quietly into the night. He has said — and says now — that he is eager to refocus all of his energies on his research. He is grateful for the vindication his lawsuits have won him; he told PROBE last month:
"I'm happy it happened while I'm still alive to see it!"

PROBE Is Proud!
When we began publishing, late in 1991, the Gallo and Baltimore cases already were several years old. Our science-writing colleagues, with a few notable exceptions — particularly, Barbara Culliton, in Nature — had bought the "scientific misconduct" bill of goods created by Crewdson, Dingell and his stooges. Phil Hills of the Times was a noteworthy Crewdsonian epigone, for which reason some of the pilloried researchers refused to talk to him.

When the journalistic pack is running one way, our reportorial instinct is to see if a case can be made for going in the opposite direction. We therefore investigated the charges against Gallo, Baltimore, Fisher and others, and discovered that, in fact, they were being framed. We have said so ever since, based on our ongoing perusal of the evidence.

We are particularly proud that in the Fisher case we were the first to report the ORI finding against his associate, surgeon Roger Poisson, M.D. of Montreal. But we thought it was no big deal (PROBE, Sept. '93). When Crewdson-Dingell blew it up to a federal case the following year, we wrote straightforwardly that the charges were B.S. — destructive B.S. — as the present settlement, three years later, confirms.

PROBE may be the only publication that has dissed all of the high profile cases from the git-go — and if there is another that has, we'd like to know. We do, of course, take some chances when we repeatedly go against the flow. But we're pleased to have done so in all of those cases. The scientists' vindication, we think, validates our own contrarian judgment! — D.R.Z.

Folo...
continued from page 2

journalism has been fairly exempt from media criticism; nobody wanted to do it. We do! We think that a debate, such as this, is good for media professionals and the readers whom we serve.

###

Correction: The correct e-mail address for quackbuster Steve Barrett, M.D., is sbinfo@quackwatch.com. We published the wrong address last month. ■

Razor...
continued from page 4

Katherine Leisure finds, some servicemen and women who suffer from the syndrome were long gone from the Gulf before combat started and Iraq fired the wells.

Per Ockham's Razor, we think infectious diseases is the simplest hypothesis at the moment, and leishmaniasis the best candidate among them. If there is more than one cause, which we doubt, researchers will have to identify first one, and then a second (or more) cause(s), and, finally, elucidate a method for differentiating between them case-by-case. — Q.E.D.
We’re appalled! There’s no nicer way to say it. We’re appalled at the New England Journal of Medicine (NEJM), America’s — some would say the world’s — leading medical research journal. We’re appalled at an editorial, written by its high-profile Executive Editor, Marcia Angell, M.D. And, we’re appalled, too, by the New York Times (Sept. 18), for what we think is biased reporting about an article that ran in the Journal (Sept. 18) and Angell’s support for it (see box).

The NEJM article is by Peter Lurie, M.D., a family practitioner and policy wonk, now at the University of Michigan, and by internist Sidney M. Wolfe, M.D., head of the Public Citizen’s Health Research Group, in Washington, a Ralph Nader organization. Their NEJM “Sounding Board” is on “unethical” clinical experiments in Third World women that are intended to establish an effective, inexpensive AZT regimen to prevent mother-to-infant AIDS transmission.

It re-presents the same arguments — which we think are fallacious — that were turned down last summer, after re-review by Health and Human Services Secretary Donna E. Shalala, as lacking in merit. As we reported here, the Public Citizen arguments were — are — tendentious, and wrong, and, if successful, will lead to increased rather than decreased numbers of infant AIDS deaths, contrary to what Lurie and Wolfe allege.

Studies Criticized
The major bone of contention is whether it is ethical to do double-blind placebo-controlled studies on Third World women, in which some women receive regimens of the drug AZT that are lower than, and hence cheaper than, the $1,000 regimen that has been proved effective in the U.S.; this regimen is called Protocol 076. Rather, must the controls now be given the Protocol 076 dosage, for ethical reasons? Lurie and Wolfe say yes.

We criticized this Naderite proposal in June issue, and reported in August that Shalala had rejected it. Now, it turns up in the NEJM — the last place we would expect to find an anti-drug, anti-medical research screed.

Worse, in Angell’s supportive editorial she compares these studies, inappropriately, with the Tuskegee Study of Untreated Syphilis. In it, poor black men were monitored, but not treated, from 1932 to 1944, when there were no effective therapies, and then from 1944 (roughly) to 1978, when penicillin was easily at hand — and certainly should have been given. Unlike Tuskegee, the Third World (mostly African) women are being offered a chance for therapy, which, if they get it — luck of the draw — and if it succeeds, will give them HIV-free babies who otherwise would be infected and die. Angell thus is incorrect when she writes:

The justifications [for the Third World HIV studies] are reminiscent of those for the Tuskegee study: Women in the Third World would not receive antiretroviral treatment anyway, so the investigators are simply observing what would happen to the subjects’ infants if there were no study.

As Angell admits, the argument can come down to a narrow disagreement as to whether all patients, and particularly the controls, are entitled to receive the “local standard of care,” or rather, the “best” current care available anywhere in a clinical experiment. Obviously, as two AIDS experts, one from the UN, and one from the American Foundation for AIDS Research, pointed out in the Times next day (Sept. 19), trying to apply American bioethical standards to African realities “shows a lack of understanding of the medical needs of developing countries.” It is also imperialist, they add, because “in declaring the trials unethical, critics are saying that American bioethical judgments should supersede those of experts in other nations” — who support the current trials.

As we wrote earlier, our view is that the studies are valid, and should be completed on medical, scientific, ethical, and compassionate grounds. Sidney Wolfe has a long-standing distaste for drug companies and medical research. It is a shame that the NEJM gives him house to assert these Luddite views, and it is doubly too bad that editor Angell, much of whose work we very much admire, lends them the Journal’s imprimatur.
Leishmaniasis...

continued from page 5

also may be effective, according to infectious disease specialist Frank Neva, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID), in Bethesda.

The good news is that with or without drug therapy, many cases remit or resolve over time. They tend to stay in remission unless the patient suffers from an immunological deficit, such as HIV infection. Gulf War vets whose ills are due to leishmaniasis thus may be able to anticipate feeling better, not worse, in the years ahead, experts suggest.

Scabs Used

“You’d expect an improvement over time, based on what we know about people who develop asymptomatic or mild infec-

tions with organisms that can cause visceral forms of leishmaniasis,” says expert Neva of NIAID.

Immunization has been used to protect people exposed to sandflies. In Iran, Israel, Russia and in some other Middle East nations, military personnel and others have been vaccinated by deliberate infection with scab material from a presumably mild leishmanial sore; this crude immunological practice is called leishmanialization. These individuals develop high, protective levels of antibodies against the organism, according to NIAID immunologist David Sacks, Ph.D., who follows this research.

Millions were treated in this way in the late ’80s, Sacks and other experts say. The problem, Sacks adds, is that the practice causes active cases of leishmaniasis, and more than a few vaccinees suffered serious, long-term illness as a result.

This method therefore has been stopped everywhere except in parts of Uzbekistan, Sacks says.

Special Subscription Offer for PROBE

You are cordially invited to reserve your subscription to PROBE, the critical, wholly-independent newsletter of science and medicine. PROBE publishes investigative articles and analyses. PROBE interprets developments in science and technology and explores their links to public policy and personal health.

YES, count me among those who support independent medical and scientific reporting. Enter my one-year subscription to PROBE at the special price of $60.

[ ] My check for $60 is enclosed. Please add a bonus extra month to my subscription.

[ ] Please bill me $60.

Fill out this form and mail it today:

Name: ________________________________________________________________

Address: ______________________________________________________________________

City: ______________________________________________________________________

State: ____________________ Zip: ______

Make checks payable to: The PROBE Newsletter, Inc. Box 1321, Cathedral Station New York, New York 10025-1321

PROBE

Box 1321 Cathedral Station New York, New York 10025