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LETTERS

Viral Marketing

I commend *Harper's Magazine* for publishing Celia Farber's report ["Out of Control," March 2004] on the corruption of AIDS science. As a mathematician who has worked for nearly a decade studying the immunological aspects of modeling HIV progression and treatment, I believe that the HIV theory of AIDS begs far more questions than it answers. The so-called mysterious or paradoxical features described in the vast scientific literature are evidence that the current paradigm is in serious need of reassessment. In the words of Stephen Hawking: "A theory is a good theory if it satisfies two requirements. It must accurately describe a large class of observations on the basis of a model that contains only a few arbitrary elements, and it must make definite predictions about the results of future observations." The HIV theory does neither.

This debate should have happened long ago, before an unproven hypothesis of an immune-destroying retrovirus was thrust upon a vulnerable public, and without being thoroughly critiqued in the scientific literature. Despite the promises made in 1984, there is still no cure and no vaccine. Instead, there has been a

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fundamental erosion in scientific and clinical-trial standards, with implications reaching far beyond HIV.

To do the best we can for those affected by AIDS—including those in Africa, where AIDS presents a clinical picture quite different from that in the developed world—there urgently needs to be an honest scientific debate.

Rebecca Culshaw, Ph.D.

Assistant Professor of Mathematics
 The University of Texas at Tyler
 Tyler, Tex.

I am a gay, HIV+ scientist, and until I read Farber's article I knew nothing about the controversies surrounding the HIV=AIDS hypothesis. The article prompted me to do my own research on the issues involved, and to consult my HIV doctor and others in the field. What I have learned has frightened me and ultimately freed me.

I had always been confused by certain aspects of the treatment of AIDS. I wondered why my friend passed away from liver failure, when his virus seemed under control. I wondered why HIV+ individuals were being told to take three FDA Class 4 drugs daily for the rest of their lives, although most drugs in this class are chemotherapies, and we don't give cancer patients chemotherapy every day. My reservations made me engage in treatment interruptions prior to 2000, when they were regarded as "suicide." My HIV

doctor recently told me that the SMART study, which concluded that treatment interruptions were contraindicated, was plagued by methodological flaws. He recommended that I stay off medications as much as possible, contrary to the advice of the American Academy of HIV Medicine. He agrees with Peter Duesberg regarding the extremely negative, immunosuppressive effects of chronic drug use and malnutrition, and that these are likely important co-factors in AIDS progression.

Consequently, I have been unable to understand the extremely vitriolic, character-assassinating responses that have appeared on the Internet following the publication of Farber's article. It does not seem radical to suggest that chronic drug use and malnutrition can make a person very ill. Why does doing so make Duesberg "crazy" and Farber a "crackpot"? And how is that kind of language even remotely appropriate in a scientific debate? Science is full of alternative theories—they're essential. In science, one does not set out to prove a particular hypothesis; one tests rival hypotheses in order to rule them out. No hypothesis regarding AIDS can be rejected until its espousers receive the funding necessary to test it.

Mark A. Biernbaum, Ph.D.
Rochester, N.Y.

Putting aside the question of how Celia Farber's lengthy article got into an estimable magazine like *Harper's*, the fact that it did requires a convincing response. Her scary article leaves readers, including this one, with the notion that current treatments for HIV/AIDS will kill everyone who takes them, validating the secret fears of everyone who does take them, irrational as these fears may or may not be. Even I can recognize holes in Farber's arguments, and I can see how nimbly she skates over certain issues. She portrays the National Institutes of Health as horrific, but it should be remembered that millions of us who a few years ago were counted as dead are still alive. In my eyes, this alone makes Dr. Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases, a hero of great stature.

Although much of what Farber dredges up is not new, the fact remains that her argument has not been answered to the satisfaction of a lot of people. I would guess that it is going to be less easy now to sweep this debate under the carpet by naming Farber and Duesberg and others "crazies" and "HIV-deniers." As Farber herself points out, there is too much money and greed now controlling the entire system of our "treatment" for that to be an effective response. It would be nice if this article encourages a more mature discussion, with less name-calling, and returns AIDS, relatively dormant of late in the consciousness of most Americans and the world, to its rightful place at the top of the public agenda. It's still spreading like wildfire.

Larry Kramer
New York City

As scientists who have devoted substantial portions of our lives in pursuit of the truth about HIV/AIDS—and speaking also for distinguished colleagues around the world, including James McIntyre, Moses Sinkala, Mark Wainberg, Waffa El-Sadr, David Ho, and Allan Rosenfield—we are appalled at Celia Farber's grossly inaccurate portrayal of AIDS research. Years of careful research have proven beyond doubt that the HIV virus causes AIDS, that antiretroviral drug treatment saves lives, and that the drug nevirapine is safe and effective in preventing the spread of HIV from mothers to their babies.

Some of Farber's most egregious errors concern nevirapine. First, she confuses long-term treatment of pregnant women with a drug cocktail that includes nevirapine, with the use of a single dose of nevirapine to prevent mother-to-child transmission. This leads the reader to believe that nevirapine in a single dose is harmful to pregnant women. Farber fails to mention the several large, randomized, Phase III studies, including the SAINT trial, that overwhelmingly confirmed that single-dose nevirapine significantly cuts a newborn's risk of HIV infection while posing no significant health risk to mothers or babies.

The record-keeping problems with HIVNET 012 were studied by an independent and irreproachable scientific panel under the auspices of the Institutes of Medicine and were found not to affect the study's conclusions in any way. Moreover, Farber ignores a key ethical reason for the lack of a placebo arm in these trials. Once AZT was shown to dramatically reduce the likelihood of transmitting the virus, it would have been unethical, according to accepted international standards, to deny protection to infants by providing their mothers with a placebo.

At one point in the article, Farber asks, "Is nevirapine better than nothing?" For the hundreds of thousands of children who have been born free of HIV because their mothers took nevirapine, the answer is an undeniable "yes." Without prevention and treatment, children across the globe will sicken and die by the millions. Our job should be to provide them with scientifically valid treatment options, not to fantasize about a world in which HIV does not cause AIDS.

Richard Marlink, M.D.

Catherine Wilfert, M.D.

Elizabeth Glaser Pediatric AIDS Foundation
Chapel Hill, N.C.

As Celia Farber reports, my sister Joyce Ann Hafford was diagnosed HIV positive in the early stages of pregnancy and was offered the opportunity to prevent transmission of the disease to her baby by enrolling in the clinical trial PACTG 1022. Her therapy included nevirapine and Combivir. Joyce experienced a severe reaction almost immediately, but it was never suggested that she stop taking the medicine. The idiots did not take her off the drugs until it was too late. My sister delivered a baby boy and died three days later from the poison prescribed to her. She never held her son.

To the scientists who underreported the deaths in the Uganda study, the lives of people like my sister meant nothing. She was just another black guinea pig, whose life was reduced to nothing more than an "oops." Meanwhile, I am left to raise her two children.

It is heartbreaking to have lost my

sister at the tender age of thirty-three. Just thinking of her brings tears to my eyes almost three years later. She was an incredible person, not a lab rat. Thank you, Celia Farber and *Harper's*, for caring enough to tell the truth. Thank you for the dignity and respect.

Rubbie King

Memphis

Behind Celia Farber's rhetoric and poorly drawn examples, there are some real issues concerning the state of HIV medicine. As a physician who began my practice twenty years ago in Greenwich Village, one of the early epicenters of the AIDS epidemic, I'd like to place her article in historical perspective.

I remember many of the difficulties we faced in the '80s and even early '90s, when there was little or no ability to treat the virus directly. Although it was clear that the loss of CD4 T-cells correlated with the risk of getting sick, we didn't understand why some patients lost T-cells more quickly than others. One of the great puzzles during this era was why it was so hard to find the virus itself. Even in the sickest patients, fewer than one in ten thousand T-cells had been infected with HIV. Leading scientists believed that HIV was the central cause, but that other co-factors were crucial to the disease process. Evidence continues to emerge today that immunological factors, particularly an over-activation of the immune system induced by HIV, are responsible for some of the loss of CD4 cells.

Understandably, some patients desperate to find a coherent explanation for their mysterious and potentially deadly disease latched on to Peter Duesberg's radical hypothesis that HIV wasn't the cause of AIDS, in the hope it might lead to another therapeutic pathway. But Duesberg offered little more than rhetoric in support of his hypothesis, and in my opinion he was remarkably ignorant about the clinical realities of AIDS.

Thankfully, the landscape of HIV treatment dramatically changed in the mid-'90s. An accurate viral-load test was developed, and the amount of virus was shown to correlate strongly with the rate of clinical progression to AIDS. Now that it is crystal clear that

HIV causes AIDS, the more relevant question is how. That question is far from being fully answered and is crucial to meeting the challenges that today's patients face, particularly with respect to the toxicity of their meds and the drug resistance that renders their meds potentially less effective.

Ten years ago, in the flush of the excitement of "the cocktail," Dr. David Ho, a researcher who was making a name for himself (with the help of a P.R. firm), asked the scientific community to stop focusing on the question of causality and to focus solely on treatment with antiviral drugs. Since then, the progress has been enormous, but no one has been cured, as Dr. Ho postulated they might be, and the prospects for antiviral drugs that meet HIV patients' current medical needs are far from certain. New approaches that complement antiviral therapies, based on new insights into how HIV damages the immune system, are desperately needed.

In my opinion, the medical leadership promotes over-prescription of HIV medicine and shows little interest in directing public funds to research new treatment approaches unless they involve brand-name drugs that resemble other drugs previously approved. Last October, *Nature* published an article on the corruption of the panels that set treatment guidelines and standards of care, citing as an example a key opinion leader in HIV research who received money from Ortho Biotech, a subsidiary of Johnson & Johnson, and whose recommendations focused heavily on a lucrative Ortho Biotech drug used in the treatment of anemia in HIV patients. Most of the doctors who sit on the panels that formulate clinical trials, or that dictate treatment guidelines, are paid consultants of the very companies whose drugs they are assessing. Some of the largest HIV clinical trials contribute so little to the development of knowledge that I have sarcastically suggested that the AIDS clinical trials group of the NIH should be moved to the Department of Highways. Like the billion-dollar highway in Alaska, they do nothing except grease the wheels of the pork-barrel system that claims its resources as an entitlement.

A great story could be written about

the small core group of key opinion leaders who set treatment guidelines, direct clinical funding, run medical education, and have a profound ability to retard research into areas that frontline clinicians plead is important. This state of affairs in HIV medicine has huge implications for the public health. It needs to be exposed by brilliant reporters with the guidance of careful editors.

Paul Bellman, M.D.
New York City

I was dismayed to read Celia Farber's article in *Harper's Magazine*, a publication I have trusted for its high standards. Her topic—namely, the difficulties and dangers of doing a clinical trial involving HIV/AIDS in a developing country—could have led to an important analysis of why such trials are needed. Unfortunately, Farber has chosen to include her own misinformed view that HIV does not cause AIDS. I will not dwell on the innumerable other problems of fact and interpretation in Farber's article. I will only say this: There is more evidence that HIV causes AIDS than there is for the cause of any other single human disease caused by an infectious agent, past or present.

A few scientists claim that HIV/AIDS researchers have not fulfilled the postulates laid down by the nineteenth-century German bacteriologist Robert Koch, who described what must be done to prove the cause of a human disease. HIV has fulfilled not only Koch's postulates but also additional criteria that have been developed through the advent of new scientific methods. That HIV is the single cause of AIDS has been concluded by every single qualified group that has studied the question, including the U.S. National Academy of Sciences; the U.S. Centers for Disease Control; the U.S. Institute of Medicine; the U.S. National Institutes of Health; the American Medical Association; the Canadian Centre for Infectious Disease Prevention and Control; the Pasteur Institute; and the World Health Organization.

In 1984, when my colleagues and I were first to claim—and in my view demonstrate—the linkage of HIV to AIDS, we showed that we could isolate HIV from forty-eight individuals

who had AIDS. Characteristics of the virus told us that, like the disease, it was new in the human population. We showed that the virus primarily targeted immune-system cells (now known as CD4+ T-cells), precisely the same cells that decline in the presence of AIDS. Thirdly, we developed a blood test based on finding specific antibodies against HIV in infected persons. With an antibody test, we were able to carry out much larger surveys, which showed that within an otherwise healthy population HIV antibodies were present at a rate approximating one "healthy" American in every 1,000 to 2,000 people surveyed, as well as in certain high-risk groups. Clinical study of those "healthy" HIV-infected persons showed they bore evidence of declining CD4 T-cells, the harbinger of future AIDS risk. These results alone were sufficient to convince that HIV causes AIDS.

At the time we published our first results, newer results obtained in collaboration with the Centers for Disease Control showed that we could pick out patients with AIDS or pre-AIDS within blind coded samples from patients whose only risk factor was having received a unit of contaminated blood. From this we were also able to identify their infected blood donor, who, without fail, went on to develop AIDS. Later, we showed that we could isolate HIV every time we found a patient with antibodies. No test in medicine is perfect, but done correctly and with a confirmatory second test, the HIV blood test developed in our laboratory comes close. Today, transfusion-associated AIDS has all but disappeared where current generation blood-screening approaches are employed.

More importantly and completely misrepresented by Ms. Farber is the history of HIV therapy. She aligns herself firmly with the strange logic of a few dangerous people who say that these medications are harming people or may be themselves causing AIDS. This is sheer lunacy. The current anti-retroviral treatments have converted AIDS from a terminal illness to a chronic treatable disease with which many people can live to a reasonably normal age, and specific therapies aimed at pregnant mothers have all but ended pediatric AIDS in the developed world. Here again, this evi-

dence alone could prove that HIV is the single cause of AIDS.

In the mid-1980s, my colleagues and I had the experience of working near several laboratory technicians who accidentally infected themselves with HIV. In every case, these heroic individuals went on to develop AIDS. This is more evidence than Robert Koch ever had before he claimed a microbe caused a disease.

I am sorry that, more than twenty-five years after the discovery of HIV as the cause of AIDS, there are those who still refuse to accept this overwhelming body of evidence. Ms. Farber's article mirrors a disturbing rise in anti-science opinion that has permeated important public-health and public-policy debate. It is surprising that *Harper's Magazine* has embraced this point of view, especially given the tragic consequences of the anti-HIV nihilist rhetoric in lives lost. This is not about *Harper's Magazine*, or about Celia Farber, Bob Gallo, or the rest of the AIDS scientific and medical community. This is about preserving human lives. In this, there is no room for the propagation of shallow and sensationalist thinking.

Robert C. Gallo, M.D.
Director, Institute of Human Virology
University of Maryland
Baltimore, Md.

Celia Farber responds:

Much of the critical response generated by my article has focused on a very brief summary of Peter Duesberg's critique of the medical consensus regarding HIV and AIDS. Although one could certainly write a long magazine article laying out the general outlines of the various critiques of the HIV hypothesis (and Peter Duesberg's is by no means the only such critique), I did not write that article. I told the stories of three individuals whose lives have been forever altered, and in one case ended, by the war on AIDS. I tried to show some of the ways in which AIDS science has been corrupted by a combination of quasi-religious zealotry and a powerful nexus of interlocking financial interests. At the heart of the piece was a whistle-blower story, the story of Jonathan Fishbein. The wrongdoing that Fishbein exposed was, among many other things, the cover-

up by the National Institutes of Health of HIVNET 012, a disastrous clinical trial in Kampala, Uganda. The drug under study was nevirapine, a highly toxic AIDS drug, made by Boehringer Ingelheim, that also happened to have killed a woman in Tennessee named Joyce Ann Hafford.

For Jonathan Fishbein, the HIVNET affair was not about AIDS or nevirapine per se; it was about scientific standards and the systematic removal of the controls that are supposed to protect research subjects and validate scientific conclusions. But what is remarkable about AIDS research is not so much the corruption—science scandals are an all-too-common feature of the daily headlines, as the Vioxx catastrophe and the South Korean cloning fiasco attest—but the missionary zeal with which the bad science is defended.

As I demonstrated in the article, the idea that what went wrong with HIVNET can be summarized in the phrase “record-keeping problems,” as Marlink and Wilfert would have it, is obscene. Marlink and Wilfert are embedded in a web of conflicts of interest that is very neatly symbolized by the fact that the organization for which they speak, the Elizabeth Glaser Pediatric AIDS Foundation, receives substantial funding from Boehringer Ingelheim, the maker of nevirapine. And, as I reported in the piece, the “independent and irrefragable” panel that reviewed HIVNET was entangled in the same web. Six of the nine panelists investigating this NIH study were the recipients of annual NIH grants ranging from \$120,000 to almost \$2 million. Some received funding from the very division under investigation. Lord help us if HIVNET is an example of what passes as acceptable science for these distinguished AIDS researchers. We can at least be grateful that the Food and Drug Administration has refused to approve single-dose nevirapine for mother-to-child transmission of HIV.

Marlink and Wilfert claim that I have confused long-term nevirapine treatment with single-dose treatment. That distinction was made very clearly in the piece. Continuous treatment is what killed Joyce Ann Hafford; her family was told that she died of AIDS. Hafford’s story not

only demonstrates the dangers of this drug but also illustrates the callous disregard with which many patients are treated by the medical establishment that speaks in their name.

Today, nevirapine, this “life-saving” drug, is being given in single doses to poor pregnant women all over the world, yet it remains unapproved for that purpose in the United States. If nevirapine is so safe and effective, why has there been no FDA approval for mother-to-child transmission? If HIVNET was such a good study, why did the FDA tell Boehringer Ingelheim to withdraw its application or face a public rejection?

It is particularly fitting that an article about scientific misconduct should engender a response from Robert Gallo, whose research has been the subject of several devastating investigations, one of which found him guilty of misconduct. Gallo, like Marlink and Wilfert, wishes to minimize the significance of the HIVNET scandal, and he entirely ignores Joyce Ann Hafford. This is typical. It seems that Hafford’s death, and those of at least five other women I have subsequently discovered, can be safely filed away with the other “lessons learned” in the long march against HIV, in much the same way that thousands of people whose lives were cut short by high-dose AZT are now forgotten.

Gallo’s letter is riddled with assertions of fact that dissolve under careful scrutiny into highly debatable interpretations of ambiguous data. But the letters section of a magazine is hardly the place to debate the fundamentals of AIDS science. And this goes right to the heart of the issue: Ultimately, the claims and counterclaims of Robert Gallo, Peter Duesberg, David Ho, or the members of Australia’s Perth Group (which has advanced its own highly original critique of the HIV paradigm) cannot be adjudicated in magazine articles or on blogs. Mark Biernbaum gets it exactly right. Only carefully designed studies that rigorously test the various hypotheses about AIDS can advance our understanding of this disease. But the suppression and demonization of competing viewpoints, and the refusal to acknowledge mistakes, especially when those mistakes cost lives, will accomplish nothing.