

# Reappraising

# AIDS

VOLUME 5, NUMBER 1

JANUARY 1997

## Non-Nucleoside Reverse Transcripts Inhibitors GET READY FOR THE NEXT MIRACLE DRUG

First there were nucleoside analogs like AZT, then protease inhibitors, and waiting on the shelf, RA reported last month, are the as-yet unavailable integrase inhibitors. Ron Piazza (HEAL-Seattle) now informs us that a fourth sort of "anti-HIV" drug has been designed, and at least one of them is already on the market. Piazza, a hospital pharmacy purchaser, sent RA a product insert for FDA-approved Viramune (generic name: nevirapine), manufactured by Roxane, and an article from the journal *Hospital Pharmacy* (31:11, Nov. 1996, p1356).

According to the article, Viramune is a "non-nucleoside reverse transcriptase inhibitor." A second one, Upjohn's Rescriptor (generic name: delavirdine), is pending FDA approval.

AZT and its brethren are also officially classified as inhibitors of reverse transcriptase, the enzyme that makes HIV DNA. But they are not reverse transcriptase inhibitors. Rather, they are fake ("analog") nucleosides, the unique portion of DNA building blocks, and act as DNA caps. When reverse transcriptase incorporates one of them onto a growing DNA chain, real DNA units cannot subsequently be added. But the enzyme—polymerase—that makes human DNA also gets fooled into using these fake building blocks, thus creating extremely toxic effects.

Viramune's manufacturer, Roxane, claims that its drug does not block the production of human DNA, just retroviral DNA, and it does this by specifically inhibiting reverse transcriptase, which means plugging the enzyme's active site so it can't accept DNA building blocks.

Piazza, who is HIV-positive but

refuses to consume "anti-HIV" pharmaceuticals, says that his hospital has received inquiries from HIV-positive people who are concerned about the toxicity of AZT. RA Board

### Rx WATCH

member David Rasnick, a PhD chemist who designed protease inhibitors for 20

years, warns those interested in these new drugs there's bound to be some inhibition of the enzyme that makes human DNA.

"The insert states that Viramune inhibits reverse transcriptase for HIV-1 but does not inhibit reverse transcriptase for HIV-2 nor the human enzyme that constructs healthy human DNA," Rasnick said in a phone interview. "As a person who has made enzyme inhibitors for 20 years, such exquisite specificity is

#### Why No Placebo Group?

One of the continuing scandals of the AIDS era has been the lack of properly controlled experiments. For example, in the studies of Viramune, the manufacturer randomly divided HIV-positive patients into groups taking Viramune alone, those taking Viramune with other anti-virals, or those taking anti-virals not including Viramune.

But what about a group taking no anti-virals?

The Medical Project Manager for the Viramune studies, Alex Dusek of Boehringer Ingelheim, which owns Roxane, said in a phone interview that standard anti-virals like AZT had already been demonstrated to be better than placebo, and that therefore further placebo studies would be unethical. When asked which study or studies demonstrated this conclusion, he cited "ACTG 019."

ACTG 019 was the first AZT-AIDS study, and the only one designed with a true placebo group—subjects taking no anti-virals at all. It was funded by AZT's manufacturer, Burroughs Wellcome (now Glaxo-Wellcome), and consisted of 282 HIV-positive subjects, roughly half taking AZT, the other half taking placebo.

The planned six-month study was stopped two months early. All the patients were given access to AZT and told that 19 of the placebo subjects had died compared with just one of the AZT consumers. Independent investigations by John Lauritsen (*The AIDS War*) and Peter Duesberg (*Inventing the AIDS Virus*) exposed several facts that invalidated not only the study's conclusions, but the study itself: 15% of the original AZT patients mysteriously disappeared from the study's statistics, 30 of those remaining required life-saving transfusions to replace blood destroyed by AZT, the death rate of the placebo group (13% over three months, 40% annualized) was curiously much higher than what physicians were used to seeing, many of the placebo subjects secretly consumed AZT, many of the AZT patients had their dosages reduced or discontinued, and just a few months after ending the study the original two groups ended up having the same mortality rate.

Trial 019 is basis for claims that anti-viral medications are better than placebo, and the Lauritsen/Duesberg critique of trial 019 is the basis for claims that anti-virals have never proven themselves against placebo in the treatment of AIDS.

remarkable, even to the point of being suspicious. It sounds too good to be true. The last time I heard of such extraordinary specificity was in 1994 when it was claimed that the Roche HIV-1 protease inhibitor did not inhibit the protease from HIV-2. That claim turned out not to be true. The Roche protease inhibitor blocks the enzymes for both HIV-1 and HIV-2. Because of this I do not accept the claims in the Viramune brochure at face value."

"You know what the AZT manufacturer (Glaxo-Wellcome) said about AZT not inhibiting human DNA production," he added, pointing out what every reappraiser knows by now: AZT and its cousins block human DNA production. This leads to the inescapable conclusion that they cause AIDS by killing immune cells and mitochondria (energy-producing organelles inside all cells). No wonder patients at Piazza's hospital desire alternatives to AZT-style drugs.

The early, manufacturer-sponsored reports of Viramune will seem familiar to anyone who remembers the excitement and promise that attended AZT introduction into the market place, and the hoopla that surround the protease inhibitors.

"The major side effect of Viramune is rash," the Roxane insert says, although "fever, nausea, headache, and abnormal liver function tests" were also "frequently reported." Unlike the AZT-class drugs, the Roxane insert assures us that Viramune does not kill fetal cells or induce cancers.

We're additionally told that the drug's

absorption and anatomical distribution were evaluated by testing on unspecified animals and "healthy volunteers." Data from these studies were not provided, but these studies helped Roxane establish Viramune's "side effects": healthy animals and humans free of accepted risk factors have no source of symptoms other than the single drug they are taking. No previous anti-HIV drug has been tested in animals

brain surgery, and rapper Easy-E's death from a collapsed lung were all blamed on HIV.)

With one pharmaceutical company having now tested animals and healthy humans with this new AIDS medication, the absence of such testing for the AZT-class drugs is more glaring than ever. Such subjects would inevitably develop the various symptoms of AID—an

embarrassment for the official view, which ignores AIDS caused by anti-AIDS drugs.

Graphs contained in the insert show the results of two brief clinical trials, one lasting a year, the other six months. The trials compared two patient groups: those having Viramune added to their ongoing AZT therapy and "controls" having placebo added. In each trial the Viramune subjects showed an average 25-50% boost in T4 counts and an average 125-160% drop in HIV "viral load." But all markers returned to their baseline values near the trials' end.

As usual, no comparison was made with a true placebo group—HIV-positive subjects taking no pharmaceuticals at all. This remains one of the most urgent and

overlooked violations of logic and scientific standards in the AIDS scandal. Finally, the drug was not tested in the absence of AZT, meaning those who are seeking an alternative to AZT-style drugs—rather than mere companions for them—have no data from which to draw conclusions.

Paul Philpott

## Sh-h-h!

Why have we not heard about Viramune before? Why wasn't its approval ushered in by media hype?

Even more curious than the lack of published scientific papers (which is true also for the fabulous protease inhibitors) is the absence of media attention announcing Viramune's arrival. According to a July 9, 1996, press release, the drug was presented at the highly-hyped International AIDS Conference in Vancouver, the same conference that for an entire week inspired daily dispatches in the nation's leading media.

Were the claims for the protease inhibitors really so much more spectacular than for this reverse transcriptase inhibitor that there was only room for one miracle on the media stage? Hardly. The press release, scripted by the ad agency Hill and Knowlton and issued on the PR Newswire, asserted that "the triple drug regimen using Viramune decreased the viral load below the limit of detection in over 50% of the patients" tested for one year.

Maybe Viramune got the hook when Conference attendees noticed that this claim did not jibe with the graphs presented in the drug's insert, which showed such effects wearing off by the one-year mark? No, since the attendees did not seem to notice this discrepancy (and even if they did, the press should have reported *that*). The Conference's Program Co-Chair is quoted as swallowing the claim whole, declaring Viramune qualified for the same praise afforded the protease inhibitors. "This study has shown that we do not have to use protease inhibitors to attain long-term suppression of the virus," said Dr. Julio Montaner of the Canadian HIV Trial Network.

So why is there not only a lack of hype, but a virtual media black-out, for this newly available wonder drug? Curiously, the other new class of "anti-HIV" drugs, integrase inhibitors, also received no media play, and PR Newswire posted the Viramune press release in its "Financial News" section with no financial discussion at all. Could it be that the drug makers are orchestrating waves of publicity blitzes, first for the AZT-class DNA terminators, now for the protease inhibitors, and soon—when those drugs fail to resolve AIDS—the reverse transcriptase inhibitors and the integrase inhibitors?

or HIV-negative humans, just HIV-positive patients. This is a major problem. The list of AIDS symptoms is so vast that physicians tend to attribute every symptom to HIV in subjects who test positive. (For example, Ryan White's death from hemophilia, Arthur Ashe's death following two bypass operations and

LIVING WITH AIDS...MAFIA STYLE "Gregory Scarpa, Sr., was a Mafioso with a penchant for brutality, extortion, and murder," begins a fascinating article in the Dec. 16, 1996 New Yorker ("The G-Man and the Hit Man"). "In 1991... Scarpa was seriously

ill: as the result of a blood transfusion [in 1986, at the age of 58], he was HIV-positive. His body had shriveled from a muscular 225 pounds to a gaunt 150, his stomach had been removed during surgery [for incurably bleeding ulcers, in association with the

transfusion], and he digested his food with pancreatic enzyme pills."

The tone and wording of the description imply that Scarpa's wasting was somehow caused by HIV rather than his lack of a stomach. Indeed the author, Frederic Dannen, attributes Scarpa's death in 1994, at age 66 while in prison for murder, to "complications from AIDS." Dannen, though, does not tell us if or when Scarpa began taking toxic "anti-HIV" cancer chemotherapies like AZT, nor does he consider the life expectancy for HIV-negative 58-year-olds with incurably bleeding ulcers who have had their stomachs removed. Scarpa lived HIV-positively and stomach-less for eight eventful years, the last two without his left eye, shot out of its socket in a pistol fight when he killed one man and injured another.

We still await an epidemic of "AIDS" among AZT-free people with health histories less colorful than the departed Gregory Scarpa's.

**IATROGENIC AIDS** In June, 1996 the CDC announced its recommendation for immediate administration of anti viral "cocktails" to health workers who are exposed to HIV-positive blood (Columbus Dispatch, Dec. 5, p1C). "In the past, the only drug available for health care workers was AZT," the report said. The cocktails contain AZT and the new protease inhibitors.

Presumably the treatments are stopped if the health worker's HIV test comes back negative, and continued if positive. "Doctors warn that there are side effects," the articles continues, "which include headaches, nausea and even pancreatic infection." Not mentioned is the fact that all those symptoms are also commonly blamed on HIV, or that AZT-style drugs can cause nearly all the common AIDS conditions: immune suppression, dementia, wasting, and lymphoma.

This is important because the CDC to date lists 49 cases of AIDS "acquired" by health workers exposed to HIV-positive blood. Are those health workers developing their AIDS conditions from HIV, or the "anti-HIV" drugs immediately prescribed to them? This question is never even asked except by reappraisers.

**SEND MORE MONEY** Rolf M. Zinkernagel, a co-winner of this

**UNCRITICAL REPORTING? NO WAY!** Advertising Age columnist Bob Garfield notices there's something wrong with the way journalists report medical news. In a Dec. 16 USA Today op/ed article, Garfield recounts how a burst of scrutiny overtook him. It occurred when he was leisurely reading a newspaper feature on obsessive-compulsive disorder, the condition where people "fixate on certain numbers, endlessly repeat phrases or gestures, and are terrified to deviate from bizarre routines."

The article reported that six to eight million Americans suffer from the disorder. "What a tragedy," Garfield wrote, "for so many people to endure the heart-breaking...Wait a minute. Six million to eight million? Enough to fill 60 Michigan stadiums? New York City? Switzerland?" Scanning similar stories for a

year's Nobel Prize in medicine, predicted an effective AIDS vaccine would be available "within ten years" (USA Today, Dec. 7). Zinkernagel, a Swiss researcher, shared his prize with Australian immunologist Peter C. Doherty, of St. Jude's Children's Research Hospital in Memphis, Tenn. They were recognized for their studies of the immune system in the 1970s.

In Stockholm to receive their shared \$1.1 million prize, Zinkernagel said that the predicted vaccine "would keep the viral infection in check so that full-blown AIDS would take between 20 and 40 years to develop," rather than the current official "incubation period" of 10 years, according to the report.

Not mentioned is that an AIDS vaccine was predicted "within two years" amid great fanfare at the 1984 press conference in which HIV's discovery was claimed by NIH researcher Robert Gallo. Also ignored is the fact that the antibodies detected by the HIV tests effectively neutralize HIV, rendering an artificial vaccine redundant and thus irrelevant.

So keep those tax dollars pouring in. The virus hunters only need another ten years.

**MORE VIRAL LOAD** Famous AIDS doctor Paul Volderding, MD, of UC-SF's med school cheered the "availability of direct measurement of the virus (HIV)." He could only have been talking about the PCR-based "viral load" test. If Volderding had read the October issue of RA, he would know that this test is indirect: rather than counting actual virus, it counts small portions of viral RNA. And it only counts those RNA bits after the PCR portion of the test has produced millions of new bits that weren't there in the first place. In this way HIV-positive AIDS patients, who have on average about ten actual HIVs per milliliter of blood, are shown to have very high "viral load" counts of around 100,000 PCR-generated RNA bits.

**WHERE'S THE VIRUS, STUPID?** Speaking of viral load, its inventor, David Ho, PhD, MD, was named Time magazine's 1996 Man of the Year. One of Ho's many distinctions is deriding Peter Duesberg and other reappraisers at an AIDS conference by wearing and distributing a button proclaiming, "It's the Virus, Stupid!" How perfectly absurd that he subsequently built his career upon a test that finds lots of HIV only by counting tens of thousands that aren't even there.

*Paul Philpott*

variety of other serious diseases—including drug and alcohol addiction, Alzheimer's disease, migraine headaches, Parkinson's disease, and diabetes—and adding up the numbers of people estimated to be suffering, he arrived at a total figure of 543 million. In a nation of 266 million, that averages out to two serious medical problems for each American. Garfield noted that his estimate was a very low approximation because of the many serious diseases that he did not consider, among them retardation, multiple sclerosis, cystic fibrosis, inflammatory bowel disease, etc.

He laments that reporters tend to "uncritically report every estimate provided us." Again we find evidence of systemic obsequiousness and laziness characterizing the journalism profession. Garfield should add that his profession has

## VIRAL BITS

## Eye On the Media

uncritically promoted HIV hysteria since its inception in 1984.

**POTENTIAL SUPPORTER** In order to block the "ravaging effects of [AIDS] spreading throughout the US," HIV-positive Americans should be "subject to normal procedures of epidemiological control," argues Armstrong Williams in his LA Times syndicated column as printed in the Charleston, SC, Post and Courier (Dec. 9, p13).

Williams obviously hasn't read the July, 1996 issue of RA, which presented CDC data demonstrating that AIDS is not "ravaging" the US: new diagnoses have been down for the past two years, AIDS remains *at least* 96% confined to the original risk groups (gays, drug injectors, their sex partners, blood product recipients), and its purported causative factor—HIV-positivity—is found in only one-per-7,000 risk-free Americans.

Williams does know about UC-Berkeley biologist Peter Duesberg, thanks to a conversation he had with Dr. Ray Hunt, identified as a "former professor of clinical surgery at the University of North Carolina, Chapel Hill." Williams, however, misunderstands Duesberg's position, thinking Duesberg attributes AIDS to a variety of infections, and that AIDS is therefore contagious, though not caused by HIV. Presumably Williams has not read Duesberg's "Inventing the AIDS Virus," which clearly documents AIDS as non-infectious and thus inappropriate for Williams' quarantine strategy. Efforts to contact Williams and Dr. Hunt by telephone were unsuccessful.

Williams is well-known as a black conservative who hosts a national talk radio show from DC. He is a rare media personality aware of and sympathetic to Duesberg, although his understanding of Duesberg's position is entirely incorrect. In addition, his proposed course of action—quarantining people who test HIV-positive—is groundless, given the facts. If you'd like to encourage him to learn the facts about HIV, AIDS, and Peter Duesberg, you should write to him at: LA Times, Times-

Mirror Building, Los Angeles, CA 90053. You may also write the SC newspaper that printed his article: Post and Courier, 134 Columbus Street, Charleston, SC 29403. It might be helpful to send both addresses a photocopy of your favorite RA issue.

**DISSIDENT JOURNALIST** When Neville Hodgkinson was head science writer for London's Sunday Times, he published some of the only thoughtful and factual newspaper articles on the subject of AIDS in the world. His articles asserted that HIV is harmless and that AIDS is caused by non-infectious factors. Imagine such perspectives advanced in the New York Times, the US's equivalent of London's Sunday Times.

During his tenure at the Times, Hodgkinson was routinely and vehemently denounced in print by fellow journalists, health officials, politicians, and political activists. Chief among them: John Maddox, then-editor of the science journal Nature, who led a boycott of the Times.

Through it all, his editor, Andrew Neil, backed him, refusing to either fire or silence Hodgkinson. When Neil retired in 1994, Hodgkinson resigned, to write a book, which was recently published. As expected, the leading British papers—including the Times—ran hostile reviews skewering it. The Times did, however, print a supportive essay by Neil, who proclaimed Hodgkinson a "real hero."

"AIDS: The Failure of Contemporary Science" (Fourth Estate Press) can be obtained at book stores in Britain, and elsewhere via The Sibylline of Books, 159-A Noe Street, San Francisco 94114-1245. Sibylline's price, including postage, in American dollars, is: \$46 US (\$48.50 California) and \$48 Canada.

Paul Philpott

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## Reappraising AIDS

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