Mistruths and Consequences

Telling antiretroviral fact from fiction is no game show

July 1, 1998 By Mark J. Huisman

Over the course of the epidemic, PWAs have swallowed a hell of a lot of pills. And stomached even more hype from drug companies, particularly when products are new and data few. All too often, early claims—echoed by corporate reps, journalists, researchers and even activists—turn out to be exaggerated or just plain false. And sometimes when a cheerleading statement is first made, the data already contradict it. (But in rare cases, community advocates can be unduly skeptical—see d4T below.) Was the ’80s rush-to-treat a tragic error? Hard to say. But if history has a pattern, you might want to think twice—unless you’re desperate and out of options—before jumping on the first study or news story; hold out for long-term studies with meaningful results.

azt/retrovir Burroughs Wellcome*, approved 3/87
The Claim: “AZT can extend life for certain HIV-infected persons if taken before the symptoms of AIDS develop.” (Dr. Anthony Fauci, NIH, 8/89)

The Facts: In contrast to NIH’s 18-month study, the three-year Concorde trial found that asymptomatic patients taking AZT by itself died 29 percent faster than those who did not. (The Lancet, 4/9/94)

The Claim: Studies of AZT in pregnant rats “revealed no evidence of harm to the fetus.” (AZT package insert, 1/88)

The Facts: Offspring of pregnant mice given AZT had an “increase in liver and lung tumors,” and “unusual reproductive organ tumors occurred in 17 percent of the females.” (NIH report, 1/97)

ddi/videx Bristol-Myers Squibb, approved 10/91
The Claim: “Treatment [with ddI] resulted in strong laboratory improvement...CD4 T-cells increased significantly.” (BMS press release, 9/89)

The Facts: ddI caused “initial CD4 gains followed by a gradual decline” after 12 weeks. (“Project Inform Fact Sheet,” 7/94)

The Claim: ddI side effects are “mainly limited to headaches and insomnia.” (Dr. Robert Yarchoan, NIH, The Wall Street Journal, 3/3/89)

The Facts: “Peripheral neuropathy occurred in 34 percent [of patients]..., diarrhea in 34 percent. Pancreatitis occurred in 9 percent...and was fatal in 27 patients.” (AIDS Clinical Care, 12/91)

ddc/hivid Hoffmann–La Roche, approved 6/92
The Claim: “Researchers have finally found a dose [of ddC] that doesn’t hurt anyone.” (“Project Inform Perspective,“ 5/90)

The Facts: “At least one adverse experience was reported by 66 percent of patients on ddC.” (NIH “Note to Physicians,” 2/93)
There is “a significantly increased risk of lymphoma” in trial arms containing ddC compared to AZT alone. (NIH memo, 6/94)

The Claim: “Hivid is at least as efficacious as ddI in delaying disease progression and death and may provide a survival advantage.” (Roche press release, 8/94)

The Facts: Compared to ddI in AZT-experienced patients, ddC resulted in “no clinical difference” in disease progression or death.

d4t/zerit Bristol-Myers Squibb, approved 6/94
The Claim: d4T was approved “in the absence of any proof that it works.” (TAGLine, 6/95)

The Facts: In AZT-experienced patients, “d4T seems definitively superior to ddI and ddC in both toxicity and efficacy,” including longer survival. (Treatment Issues, 5/95) (Note: Later studies found that any antiretroviral taken alone is inferior to three-drug therapy.)

3tc/epivir Burroughs Wellcome*, approved 11/95
The Claim: “3TC and Retrovir have the most prolonged and pronounced effect of any drug regimen studied to date.”(Burroughs Wellcome press release, 11/94)

The Facts: For people with two years of AZT experience, “adding 3TC proved little better than adding ddC.” (“Treatment Issues,” 2/95)

saquinavir/invirase Hoffmann–La Roche, 12/95
The Claim: The original hard-gel form of saquinavir, taken at the standard dosage in combination with nukes, provides a “meaningful antiviral effect.” (Roche officials, Retrovirus Conference, 1/95)

The Facts: “The dose we are stuck with...is not optimal.” (Dr. Fred Valentine, chair, FDA Antiviral

Drugs Committee, 11/95)
“Roche went to market in November 1995 knowing that the dosage and formulation of saquinavir...were suboptimal and might lead to cross-resistance with other protease inhibitors.” (“TAGLine,” 7/97)

The Claim: “Cross-resistance with other protease inhibitors [taken after Invirase] is considered unlikely.” (Roche press release, 2/96)

The Facts: A federal trial of PWAs switching from Invirase to other protease inhibitors found evidence that cross-resistance had developed. (“TAGLine,” 7/97)

ritonavir/norvir Abbott Laboratories, approved 3/96
The Claim: “Ritonavir was generally well-tolerated with occasional increases in liver enzymes.” (Abbott’s Dr. David Pizzuti, Community Symposium on Protease Inhibitors, 1/96)

The Facts: “85 to 100 percent of those treated with ritonavir...reported at least one adverse event,” most commonly gastrointestinal distress and elevated liver enzymes. (The New England Journal of Medicine, 7/7/95)

indinavir/crixivan Merck & Co., approved 3/96
The Claim: “Nephrolithiasis [kidney stones] occurred at an incidence of 2–3 percent.” (Merck’s Dr. Emilio Emini, Community Symposium on Protease Inhibitors, 1/96)

The Facts: “Nine patients [of 90] had kidney stones.... In earlier studies, seven of 76 patients experienced kidney stones and discontinued therapy.” This ratio is 10 percent. (Dr. Roy Gulick, report on Merck trial, International AIDS Conference, 7/96)
“Signs and symptoms of kidney stones and flank pain occurred in two of 10 patients.” The ratio here is 20 percent. (Dr. Roy Steigbigel, report on Merck trial, International AIDS Conference, 7/96)

nevirapine/viramune Boehringer Ingelheim, 6/96
The Claim: In early studies “some patients experienced side effects (fever and rash)..., but a different [standard dose] seems to have alleviated this problem.” (B-I, Nevirapine fact sheet, 2/93)

The Facts: “Rash occurred in 37 percent of patients.... One potentially life-threatening side effect is Stevens-Johnson syndrome, severe rashes [that] may require skin grafts.” (“Project Inform Perspective,” 9/96)
“Viramune must be discontinued in patients who develop a severe rash, or a rash accompanied by constitutional symptoms such as fever, blistering, oral lesions, conjunctivitis, swelling, muscles or joint aches, or general malaise.” (Viramune package insert, 1/98)

delavirdine/rescriptor Pharmacia & Upjohn, 4/97
The Claim: “Rescriptor [in combination with a nuke]...can be used to treat HIV infected patients, including...asymptomatic patients.” (P&U press release, 5/97)

The Facts: In “asymptomatic” patients with CD4 counts between 200 and 500, “no significant difference in [viral load] was noted after a year” between those taking delavirdine and AZT vs. AZT alone. (AIDS Clinical Care, 10/97)

nelfinavir/viracept Agouron, approved 3/97
The Claim: Nelfinavir shows “little cross-resistance with the three other FDA-approved protease inhibitors.” (Agouron’s Amy Patick, International Drug Resistance Workshop, 7/96)

The Facts: “When switched from nelfinavir to a second protease-based regimen,” study participants had “a 25 percent success rate.” Nine out of 12 patients had small, temporary or no viral load reductions—usually considered to suggest cross-resistance. (Mike Barr, “Data Dish,” POZ, 1/98)

The Claim: “In laboratory studies, HIV obtained from five patients who became resistant to Viracept was not resistant to other protease inhibitors.” (Agouron ad, Positively Aware, 1/98)

The Facts: “The study Barr quotes...is far more robust than the small set of in vitro [test tube] observations that Agouron felt valid enough to cite in its ads to imply that the drug will not produce cross-resistance.…In response to repeated complaints from Project Inform, Agouron has agreed to remove the misleading statements from its ads.” (Martin Delaney, Project Inform, Letter to the editor, POZ, 4/98)

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