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Serious Adverse Events
An Uncensored History of AIDS
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Reviewed by Mike Chappelle

When *Harper's Magazine* published "Out of Control: AIDS and the Corruption of Medical Science" (March, 2006) by investigative medical journalist Celia Farber, it set off, according to the *New York Times*, a "firestorm in the media and among AIDS researchers" (*NYT* 3/13/06). In modified form, that article reappears as a concluding chapter in Farber's *Serious Adverse Events: An Uncensored History of AIDS*. The book is a collection of updated articles from her twenty years in AIDS reporting, from which a disturbing picture emerges that challenges virtually everything the public mind has been led to believe about AIDS.

Briefly, the article/chapter that appeared in *Harper's* details a disastrous clinical trial in Uganda that was used to launch a highly touted AIDS drug, Nevirapine. Nevirapine is administered, in certain parts of the world, to pregnant women for the prevention of mother to child transmission of HIV, the virus held to be the cause of AIDS by most doctors and scientists.

Although in an earlier study, the drug had shown alarming toxicity, and Canada had turned down the German Pharmaceutical giant Boehringer Ingelheim's application for approval of Nevirapine, the National Institutes of Health (NIH) in 1997 provided major funding for a trial of the drug in Kampala, Uganda. This was to be a randomized, placebo controlled, double-blind trial. However, as Farber reveals, nearly all these parameters were soon shifted and amended; in the end the trial was neither randomized, placebo controlled nor double-blinded.

Not only this, but documents were altered and records failed to make clear which patients had been given Nevirapine, when they had gotten it, or even if they were still alive at various

follow-up points. Furthermore, deaths, unless they occurred within a certain timeframe at the beginning of the study, were either not reported or downgraded to “serious adverse events” while truly serious adverse events were themselves downgraded to less serious ones. In addition, principle investigators running the trial had generally not even seen the trial patients, and when evaluating the adverse events they had relied almost entirely on secondhand summaries. These shocking revelations were brought to light during two follow-up inspections, prompted when Boehringer, filed for a license from the FDA in 2001 to sell the drug in the United States. In the wake of the revealed infractions, it is not surprising that the FDA refused to license Nevirapine for use in the U.S. And at a meeting with the NIH and the FDA, Boehringer was instructed that, if it wanted to avoid a public rejection, it should withdraw its application. Although Boehringer did finally withdraw its US application, by then the drug had already been widely heralded in the medical press, recommended by the World Health Organization, and was being shipped to maternity wards across the developing world. What followed was not, as one might expect, a recall, but on the contrary, a cover-up. Top officials in the Division of AIDS at the NIH attempted to rehabilitate the Uganda trial by initiating an in-house “remonitoring review” in 2003. These officials rewrote a report of the trial in such a way as to minimize toxicities, deaths, and record-keeping problems, allowing them to conclude that Nevirapine was safe and effective.

Despite this rewrite, a conscientious medical officer, this time at the NIH itself, once more raised safety issues and brought them to the attention of a branch chief, who in turn brought the issue, once again, to the attention of the FDA. The Division of AIDS attempted to reprimand this branch chief for insubordination for notifying the FDA. However, when the then recently hired director of the Division’s Office for Policy Research Operations, Jonathan Fishbein, was asked to sign off on the reprimand, he refused, and was fired. Fishbein then went public, bringing evidence that the Division of AIDS had covered up the Uganda study’s failures to various officials at the NIH and to the U.S. Congress. In 2004 he applied for whistleblower status. The chapter closes with Fishbein’s being granted whistleblower status, Nevirapine still unlicensed in the United States, but prescribed elsewhere.

Of course context is everything, and, as medical historians, sociologists and anthropologists repeatedly remind us, medical practice is dictated not by “progress” or “objective” science; but rather, is the outcome of negotiations between and among elaborate “webs of interests.” In *Serious Adverse Events*, this notion of “webs of interests” translates roughly to “financial megalopolis,” which Farber says consists of government, academia, and the biotech and pharmaceutical industries. Medical scientists who seek successful careers must reduce the scope of the research questions they ask, tailoring their work into agendas that do not clash with the financial and ideological needs of this web/megalopolis. The “best and the brightest” of those who conform to these restrictions become “experts,” their shared views producing an “expert consensus,” which although portrayed as “enlightened objectivity” is, in fact, subjected to the market, and the market’s dependence on stability and short-run profit. It is by situating the Nevirapine scandal into the overarching political economy that Farber is able to make comprehensible the story of medical science run amok, not only in Uganda in 1997, but in the field of AIDS from its inception.

While historians trace webs of interests back to at least the late 17th century, Farber, as a contemporary journalist working the AIDS beat, begins her narrative with two formative pre-AIDS medical events of the 1970s: the swine flu fiasco and the war on cancer. She writes how institutions and scientists involved with these two failed programs later dictated an “expert consensus” on AIDS etiology that focused exclusively on viruses while minimizing or neglecting other causal factors, from nutrition and immune status to social and environmental ones. Once the “expert consensus” settled on HIV as the cause of AIDS no serious questioning of the HIV hypothesis was permitted.

There is perhaps no clearer demonstration of the strength of the web/megalopolis at work in medicine, and the conformity it requires, than citing the case of the most prominent scientist who resisted it, Peter Duesberg. In Farber’s opening chapter she documents what eminent evolutionary biologist Lynn Margulis has called “the troubling censorship and punishment of a tenacious scientist seeking answers.” Duesberg, one of the youngest inductees ever voted into the

National Academy of Science, and one of the most generously funded, became a pariah virtually overnight after he challenged the consensus that HIV is the cause of AIDS. Farber writes how Duesberg, after he dared question the HIV hypothesis, was stripped of government funding, a proper lab, grad students, and invitations to conferences. Most interestingly, Duesberg, after years in the desert, is making one of the most unlikely scientific comebacks of all time, not in AIDS, but for his prominent role, now under way, in revolutionizing how scientists think about cancer. It remains to be seen what impact his return to respectability will have on the field of AIDS.

Farber, unlike the vast majority of mainstream journalists, themselves caught up in the web/megalopolis, has critically reported on the many dire consequences that followed from this reified consensus that HIV=AIDS=Death. Chapters recount the rise and fall of purported “life saving” drugs and treatment protocols, which, despite their having received rapturous support in the medical and popular press, consistently proved to be failures, such as the first FDA drug approved for the treatment of AIDS in 1987, AZT. Approval of AZT reads like a dry run for Nevirapine, only at that time the “clinical material” consisted of AIDS sufferers in the US. Like Nevirapine, AZT was known to be extremely toxic, and its approval was based on a single study that has long been declared invalid, a study designed to be double-blind, but which in fact was not. Farber notes significantly that in 1989, the last survivor of the original trial died after being on AZT for three and a half years, while the longest surviving patient not on AZT had at that time lived for eight and a half years.

In addition to AIDS therapeutics, key issues tackled by Farber include the inescapable ambiguity of HIV antibody tests, the overestimation of AIDS cases in Africa, and co-opted activist AIDS organizations. All of these, in their own way, have continuously fanned the initial hysteria, manufactured in the 1980s, that AIDS was an inevitable death sentence, which would spread rampantly along lines of heterosexual sex.

Celia Farber has chronicled decades of duplicity in the field of AIDS with tenacity, integrity, and an exemplary willingness to challenge authority, demonstrating investigative

journalism at its best. In *Serious Adverse Events* she provides us with a prime example of the horrifying degree to which medical research and practices have been failing the public health, and the success of the “financial megalopolis” in keeping this record of failure from the public. With a respected publication like *Harper’s* doing the fact-checking, her investigative work has gained a long-overdue respect and visibility.