The Viral Lowdown: Pharma Flubs Phase IV

FDA to Activists: Be careful what you wish for.

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When the FDA finally yielded to years of activists yelling “Drugs into bodies!” and mandated accelerated approval of lifesaving meds, HIVers heaved a sigh of relief. Now, four years and many nasty drug side effects later, treatment troops are tooting this tune: “Where’s the post-marketing data?”

A drug passes through three phases to get green-lighted; Phase IV, conducted once the product is on the shelf, investigates effects of its long-term use in real-life situations, such as in combination with other meds. AZT, the first AIDS drug, flew through clinical trials in 1987 to meet a desperate need -- and set a precedent for approval speed. But under the 1997 Modernization Act, post-marketing studies became FDA recommendations rather than requirements; as a result, few companies conduct adequate post-approval research.

“Industry has no incentive to carry out Phase IV studies,” said Gregg Gonsalves, of the Treatment Action Group (TAG). Project Inform founder Martin Delaney agrees: “Companies want to coast along in the light of whatever short studies showed the drug worth licensure -- they aren’t interested in searching for warts.”

But in the wake of the FDA’s recent banning of potential hazards such as Rezulin for diabetes and Fen-Phen for obesity, the need for post-marketing data has become clear. “Sadly, there is a gap between what activists call Phase IV and what drug companies call it,” said Delaney. “Long-term studies should compare drugs, provide success and failure info and reveal side effects.” Current studies, he said, are done by marketing teams “interested only in what will help them sell more drugs.”

Yet Gonsalves said this void may soon be filled. He was part of a coalition that has pushed the NIH to launch Phase IV to test the best time to start and stop anti-HIV therapy. “We need this research,” Gonsalves said, “because people are making decisions in the dark.”

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