What If You Take HIV Meds but Your Immune System Doesn't Rebound?

A group of "immunological nonresponders" wants the FDA to grant them orphan disease status.

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Possibly tens of thousands of people living with HIV are taking daily meds but not seeing a response to the treatment. In other words, their CD4 counts aren't significantly rising, leaving them at higher risk for numerous infections, cancers, heart attacks and death. STAT News profiles this often overlooked population—notably Nelson Vergel and Matt Sharp—known as immunologic nonresponders (INRs) and their future treatment hopes, in a recent article.

It's difficult to know how many INRs there are, partially because the definition of an INR varies from study to study. But according to STAT, most experts agree on one figure: fewer than 200,000. Why this number?

It's an important benchmark because a group of INRs is trying to persuade the Food and Drug Administration (FDA) to grant them orphan disease status—and for experimental treatments developed for them to be designated as orphan drugs. For this to happen, they have to prove that there are fewer than 200,000 INRs in the United States.

An orphan drug status means that biotech companies receive significant financial and research incentives to develop new treatments for a very rare disease.

STAT points out that there are fewer drugs in the pipeline for INRs, although in the past decade there had been promising developments, specifically interleukin-2, interleukin-7 and a process in which CD4 cells were genetically altered to make them immune to infection. Unfortunately, each failed to materialize. Interleukin-2 simply didn't work; the company developing interleukin-7 went bankrupt; and, despite very promising results, Sangamo Therapeutics, the company behind the gene-altering treatment, decided to direct the technology toward HIV cure research, not toward salvage therapies for INRs. (You can read about Sangamo's genetic research here.)

Nelson VergelLynn Lane

In related POZ news, last year the FDA approved Trogarzo for multidrug-resistant HIV. The intravenously infused med was granted orphan drug designation. For more, click #Trogarzo.

And last summer, POZ profiled INR Nelson Vergel (pictured above) and his advocacy for salvage therapies. To read about the POZ Hero from our July/August issue, click "Built to Survive." In addition, you can read an opinion piece in POZ by Matt Sharp, another INR profiled in STAT; it's titled "The Unintended Consequences of AIDS Survival."

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