**Testimony of Frank Oldham, Jr., President and CEO, National Association of People with AIDS, before Senate HELP Committee, Subcommittee on Primary Health and Aging**

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The National Association of People with AIDS, known as NAPWA, is the largest and oldest patient advocacy group for people living with HIV/AIDS. We're also the seen as the most trusted voice by the community because of our long standing independence.

Next year, NAPWA has a bittersweet milestone. We turn 30 years old. I say bittersweet because we'd like nothing better than to see an end to this epidemic, which has taken such a toll on the least fortunate of our society. On the otherhand, we're thrilled to be alive to do the good work our organization needs to do to educate and inform about the needs of people living with HIV/AIDS. These are 30 years that dear friends of mine, lost in the early days of the AIDS epidemic, never had a chance to live.

So with them in mind, we thank the pharmaceutical industry, the FDA, and brilliant researchers for creating anti-retrovirals. I'm living proof that they work.

But these are far from perfect drugs. According to recent CDC studies, less than 25 percent of people prescribed anti-retrovirals stay on the treatment.

Some say this is because they can make you nauseous, especially when one first starts taking them. Others stop because access to them has stopped. They do increase the risk of long term organ damage. And while premature death at age 70 because of ART is preferable to premature death because of AIDS at age 30, NAPWA does believe we can work to support research that will find even better treatments that will give those of us living with HIV/AIDS the same quality of life and expectancy as those who don't have HIV.

One of my friends and colleagues who has been taking antiretrovirals for nearly 20 years, is thrilled to be alive because of them. But he takes an additional 10 pills a day to manage the side effects of this class of medication. Keep *that* in mind when factor the cost burden of the status quo.

So our 30th anniversary is not only bittersweet because the epidemic is still here. It's bittersweet because while we are fortunate to have treatments that dramatically extend survival, they are not an acceptable end-game. We can and must do better.

For the last two years at major international HIV/AIDS research conferences, NAPWA has hosted symposiums on functional cure research. This area of research involves creating triggers for the immune system to allow patient's own nature self defense shield kick-in and work against HIV. This involves

creating therapeutic vaccines that could be given to people living with HIV after they are already infected.

To explain, many children get chicken pox. Despite being treated for it, the virus lingers slowly in the background for the rest of that person's life. In most cases it remains in check. But in some people, as adults, it emerges as Shingles. Researchers are working on a shingles vaccine – given despite the organism's presence already in the body. So too would be the case for therapeutic vaccines for HIV.

Impressive results have been emerging recently. One company based in Gaithersburg, VIRxSYS, has shown that its therapeutic vaccine, when used in monkeys that were intentionally highly infected with the monkey version of HIV, was able to achieve a functional cure in some of the monkeys. At two years, no detectable viral load was recorded, even in the most hard to reach reservoirs of these animals.

Another company based in Norway, Bionor Pharma, has shown that its therapeutic vaccine reduced the viral set point – or base line – in patients significantly better than placebo. This could offer an insurance policy treatment for all of those people who either have no access to ART, can't afford the treatments, no longer respond to them, or who simply stop taking them. You can't stop taking a vaccine. Once it's in you, it's in you.

Our symposium featured many other vaccine candidates, but these two tell an interesting story. The Norwegian vaccine development will not move into phase 3, the final human test before presentation to FDA for approval, unless a pharmaceutical company steps forward. Costs of these trials are enormous, and the small biotech companies cannot do them alone. But the story of the first company, based here in Gaithersburg, is all too familiar to us. No funding was made available, and the technology now sits idle. We will never know if it is a breakthrough in humans unless something changes fast.

Many speculate why these – or any HIV therapeutic HIV vaccine candidate – have not been licensed by pharmaceutical companies. We don't know the answers and should be careful not to project. However, one prevailing thought is that eliminating a highly profitable daily treatment – one taken for years if not decades of a patient's life – is preferred to the sale of a significantly less expensive immune-based therapy.

Regardless of the reason, with over 30 HIV treatments on the market, but over 20 of these are antiretrovirals – a single class of therapy – we must do something to stimulate new innovation. Industry is not bringing us new breakthroughs – only mildly improved versions of the same class of treatment we first saw in 1987 when AZT was approved as the first antiretroviral.

Therapeutic vaccines are only one category of immune-based strategies that are underfunded and appear not to be the blockbuster sized drug that industry embraces. There are others. We are eager to see these products reach the market – and for companies to make a fair profit for their brilliant research and investments – but under the current system, we're not seeing the advances despite good science.

The National Association of People with AIDS will be here as long as there are people living with HIV/AIDS. We want to be partners with Senators, members of Congress, and industry representatives who are prepared to roll up our sleeves and take an honest assessment of what does and does not work when it comes to incentivizing drug development in HIV.

We applaud Senator Sanders for thinking creatively to figure out new incentives that could result in faster results. We do not want to be coming back to the Senate 30 years from now. We want a cure, and I'm here to tell you that the HIV community will not rest until we have one. All possible incentive options should be put on the table for discussion if we are ever going to incentivize the type of breakthrough that can provide a bridge to a complete cure.