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Good morning. I'm Elliott Millenson. I'm here today to present the true history of home AIDS testing, which differs substantially from the fairy tale history presented by FDA. It's important to correct the record - to provide perspective - as it has great bearing on your deliberations. In 1985, I founded the company that developed the world's first home AIDS test, although I no longer have any financial interest in AIDS testing.

FDA has blocked home AIDS testing for two decades despite strong scientific support and a compelling public need. Forsaking its role as the watchdog of America's health, FDA became the lapdog of special interests. Yielding to political pressure, FDA ignored unambiguous science and banned home AIDS tests, sentencing tens of thousands of Americans to death.

Early History of AIDS Testing

When AIDS first appeared in the U.S. in the early 1980s, many of those infected with HIV organized and demanded treatments. These AIDS activists demonstrated and lobbied aggressively at all levels of government with particular focus on influencing FDA. Once an HIV test was developed in 1985, making tests as widely available as possible would have been the obvious and logical public health response to a fatal, sexually transmitted disease. But AIDS

activists opposed testing - fearful of its impact on their lives. They were afraid that employers, government, and sex partners would want to know their HIV serostatus. So public health officials let the fears of the infected prevail over the rights of the uninfected.

Promoting condoms - despite their high failure rate - became the cornerstone of our national “don’t ask-don’t tell” approach to AIDS prevention. The idea - first promulgated by those infected with HIV - is that your partner doesn’t need to know whether you’re infected, you just have to use condoms. Condoms help. But the truth is, having sex with an HIV infected partner is never “safe”, even with a condom. A sound public health policy would strongly advocate testing as well as condoms. It would make HIV tests widely accessible and would encourage knowing your partner’s HIV status. But, public health officials, who knew widespread access to testing could help prevent the spread of AIDS, rejected the clarity of science for the fog of politics.

History of Home AIDS Testing

I conceived the idea for a rapid home AIDS test in 1985 – over 20 years ago. By 1986 my company’s scientists had determined it was technically feasible to develop a safe, effective, and affordable test. So, I met with FDA. I revealed my company’s research showing the majority of Americans wanted a home HIV test, and that many people would only get tested using a home test - findings

later confirmed by CDC. I explained government could even give away home tests to those who could not afford one – an approach that would be more effective and economical than a brick and mortar approach of funding hundreds of independent testing clinics. FDA told me they would “probably never” consider a rapid home AIDS test.

FDA Bans All Home AIDS Tests

After meeting with FDA, rather than developing a rapid AIDS test we developed a vastly inferior product - a blood collection kit. We felt there was a greater chance of overcoming FDA's opposition to home AIDS testing with this as an initial step. In 1987, after successful clinical trials at Johns Hopkins, we submitted to FDA our premarket approval application (PMA) which demonstrated our test's safety and efficacy.

But a perfect political storm hit home AIDS testing. AIDS activists and those with a financial interest in HIV testing swiftly made their opposition known to FDA. Testing clinics, whose funding was linked to the number of tests performed, aggressively lobbied FDA and Congress to block approval of our test.

In March 1988, succumbing to this political pressure, FDA published criteria banning all home HIV tests – our blood collection kit as well as rapid tests. FDA concocted reasons for its ban; foremost among them was the claim of a significant risk of suicide with a home AIDS test. Despite data showing a third of Americans preferred a home test, FDA denied them this choice, claiming it was

necessary to compel them to have face-to-face counseling to protect them from committing suicide. Let me be emphatically clear. There was never any data to support FDA's absurd claim. In fact, there was substantial data presented to FDA by my company as well as by experts in the field of suicide prevention, that suicide was not a risk. FDA also invented a plethora of other baseless arguments against home testing: people would engage in risky sexual behaviors without face to face counseling; that during the window period, people would spread the disease if they received a negative result from a home test, but not if they received their result in a clinic. There were no data to support these claims.

But FDA was not interested in data. FDA was only interested in appeasing special interests. In announcing its 1988 ban, FDA obfuscated, making the seemingly reasonable announcement that they had established five criteria for reviewing a home HIV test application. FDA indicated they would not review any applications that did not meet all of their five criteria. Let's take a look:

1. The [HIV test] kits must be labeled and marketed for professional use only within a comprehensive health care environment, for example, hospitals, medical clinics, doctors' offices doctors' offices, sexually transmitted disease clinics, alternative test sites and mental health clinics.
2. The kits must provide for the collection of a venipuncture or other appropriately validated sample by one who is recognized by a state or

local authority to perform such procedures.

3. The testing sequence for all samples collected with the kits must include use of a licensed screening test for antibody to HIV and, for those samples testing positive by the screening test, the use of an additional more specific test, that is, the Western blot or comparable test. It is recommended that a licensed, more specific test be utilized. However, the Agency may accept a properly validated unlicensed test until licensed tests are more widely available.
4. The instructions for sample collection, storage, shipping and testing must conform with or be validated as equivalent to the package insert instructions for the specific licensed antibody test kit used to test the samples.
5. All results of testing must be reported directly to a professional health care provider for reporting and interpretation of the results of the test to the requestor, as well as for counseling of the individual.

We can stop at the first requirement because it's a showstopper. The criteria say that FDA will not even review an application for any HIV test unless a professional health care provider administers it in a medical facility. FDA's criteria represented a de facto ban on home AIDS testing. So, FDA refused to

even review my company's application, although it contained data responding to the very concerns FDA had raised.

I persevered and continued to fight, often a lone voice. AIDS activists fought back. Armed with no data to support their claims of the dangers of home AIDS testing, they continued to vehemently lobby against such tests. They testified against home AIDS tests at Congressional and FDA hearings. They lobbied in numerous states as well, including New York, Florida, Texas, and California and successfully pushed for legislation banning home HIV tests.

In 1990 - 3 years after our submission - I sued FDA, seeking to compel them to review our data. To settle that lawsuit, FDA finally agreed to review my application and hold an Advisory Committee meeting. In its story on the settlement, The New York *Times* reported that "[FDA's CBER Director Paul] Parkman said the agency was not softening its opposition to home testing kits that would check blood samples and give a result instantly, tests that are theoretically possible although none has been formally proposed." The usual suspects showed up at FDA's 1990 Advisors meeting to express their strong opposition to our home AIDS test. The laboratory and medical associations. The clinics. The activists. FDA and CDC also expressed grave concerns about the risk of suicides, and other completely unsupported issues with no scientific basis. They argued that face to face counseling was essential despite CDC data revealing 80-90% of people received no pre or post test counseling with their HIV

test using existing test alternatives. Only one of FDA's advisors had the courage to vote for approval. Disturbed by FDA's attempt to bias its own Advisory Committee, this advisor commented, "It was almost as if this matter was brought before FDA's subcommittee on non-approvability."

After FDA's 1990 Advisors meeting, I sued FDA again – seeking an unbiased review. In settlement of that lawsuit three years later in 1993, FDA agreed to again review my application, this time "as expeditiously as possible". The FDA Commissioner's Office indicated, though, that I would need to build political support for our test and reverse state laws before it could be approved. Until then, their 5 criteria from 1988 would still officially be in place.

So, over the next two years, I met with AIDS interest groups and leading AIDS activists, calming their concerns about our test. We formed an Advisory Group composed of leading AIDS activists, physicians, and scientists. We received support from minority groups like NAACP and National Council of La Raza. Leaders in Congress, on both sides of the aisle, supported our test after we met and they learned about our test's potential to save lives. Newspapers like the Los Angeles *Times* supported home AIDS testing on their editorial pages. And, we worked with the states – which reversed their laws that banned our test. In short, we gave FDA the political cover they had requested.

So in 1994 – with essentially the same data we'd brought to FDA in 1987 – FDA's Advisory Committee met and supported approval of our test. The clinics, which feared competition, still opposed our test. So despite its promise to

“expeditiously review” our application, FDA took two more years before it ultimately changed some of its criteria (not the ones which restrict a rapid HIV test) and approved my company’s product in 1996. I left the business shortly thereafter. At that time, there was still strong political opposition to a rapid home test, and FDA had still not changed its criteria that precluded approval of such a test. Ten years have now passed.

Home AIDS Testing Today

Today, FDA is reconsidering its opposition, stating as its reason that:

“With improved test kit technology (ease of use, freedom from biohazards, and excellent performance characteristics), we believe it may be feasible to identify regulatory criteria for home-use HIV test kits.”

The real reason FDA’s position has softened is a warming political climate, not improved test kit technology. FDA’s ban – not a lack of technology – is the reason no company has approached FDA seeking approval for a home AIDS test before now. Major health care companies are well aware that FDA has had a longstanding bias against home AIDS tests.

Let me provide perspective. In 1994, my company – by that time a Johnson & Johnson subsidiary - had developed a rapid home-use HIV saliva test which had cost and performance characteristics as good or better than the rapid tests available today. We did not seek approval because FDA made it clear they would not even consider an application. An entrepreneur can afford to fight FDA. A large company with a diverse product portfolio is afraid to antagonize the regulator of its pipeline.

I have no doubt there are companies with strong development and manufacturing expertise which have proven consumer marketing and distribution capabilities that could enter this arena with even more effective and efficient products than what we had in 1994. They must be encouraged to do so.

For 20 years, devoid of data, FDA invented the theoretical risk of suicide to do the bidding of AIDS activists and competitors of home tests - testing clinics and labs. When politics isn't its guiding light, FDA relies on science. Last month, for example, an FDA Advisory Committee recommended a black box warning label on stimulants. The *New York Times* reported, "F.D.A. officials said that warning patients about a theoretical risk might scare many away from needed treatment. 'We still believe that what you tell people should reflect the available data,' said Dr. Robert Temple, director of the agency's office of medical policy." FDA's mandate is clear: to be above politics and make life affecting decisions based on data, not unsupported theories. Yet at today's meeting FDA is still raising baseless theoretical risks it claims are associated with home AIDS tests. In its background materials for this meeting for example, FDA states:

- Home use HIV test kits may lead to coercive testing for HIV.
- Inappropriate use of the test or test result, including misinterpretation (e.g. relying on the test to provide an accurate result after a very recent exposure), may lead to a false sense of security. Continued high risk behavior may result in additional HIV infections.
- Home-use test kits rely on informational material for pre-test and post-test counseling. Without live counseling there is a potential for adverse

outcomes following obtaining a positive test result.

- Home –use HIV test kits may lead to coercive testing for HIV.

Home AIDS testing can reduce the spread of infection – both from the 25% of those HIV infected Americans who don't know it and are infecting others - as well as from the alarmingly high number of those infected with HIV who know they are infected and don't tell their sex partners. More than a million Americans have become infected with HIV while FDA has raised the unsupported concern that home testing will lead to suicide and an increase in "risky behavior". In fact, CDC data reveal it's safer to just test and know your partner's status, even taking into account the window period inherent with any HIV test, than to just rely on condoms. So the safer sex is sex with testing. Yet, FDA has allowed condoms to be promoted as "safe" despite their limitations, while contending with no scientific basis that home AIDS tests are too dangerous to allow on the market. We need both in our arsenal to fight AIDS.

Having served in the US Public Health Service, I know that most people in public health, including FDA, care deeply about doing the right thing for America. The political climate for home AIDS testing is warming. Yet FDA continues to raise baseless risks about home AIDS tests and sweep the true history under the rug. FDA must take affirmative actions to provide Americans the choice of a home AIDS test – and send a clear message to industry and consumers that it is ready to regulate home AIDS tests based on science not politics.

Thank you.