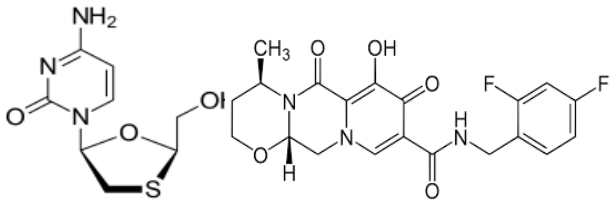
Dovato: A New Chapter In HIV Treatment

Two Student Team
Names Deleted

I. Introduction

Since the early 1980s, approximately 76 million people have been infected with the human immunodeficiency virus, or HIV. About 38 million people are still dealing with this disease today. In recent years the rate of infection has declined. This reduction has been a result of both increased awareness and effective medications. Various companies have scrambled to fight this serious issue, but none have been as successful as ViiV's Dovato.

Dovato gained FDA approval in 2019 and was released to patients the same year. This medicine was important because it was the first treatment that allowed all HIV patients to take an effective treatment (did not have to be on antiretroviral treatment already). Dovato is a treatment, not a cure, but it can keep HIV under control to a level of undetectability. Additionally, Dovato is the first medication to combine just 2 medicines (Lamivudine and Dolutegravir) into 1 pill, drastically decreasing side effects and complications with prescriptions. In clinical studies, Dovato has shown to be just as effective as a 3 drug regimen.

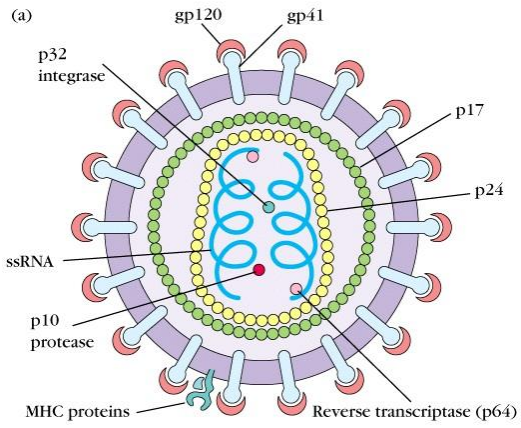


Along with saving countless lives, the development of these drugs has proven to be largely profitable for companies such as ViiV. Dovato's biggest competitor, Biktarvy, sold $3.3 billion in the first half of 2020 alone. Dovato hopes to eat into these profits as it gains popularity among patients. In the first half of 2020, Dovato, and its sister drug Juluca (also manufactured by ViiV), brought in $476 million in sales. In the coming years, Dovato is on track to surpass Biktarvy in sales as it becomes the biggest drug for HIV treatment. With the continued development of drugs such as Dovato, we should continue to see a steady decrease in HIV cases worldwide and potentially eliminate it altogether.

II. Condition Background - HIV

HIV, or the human immunodeficiency virus was first discovered in June of 1981. The virus originated from a chimpanzee in Central Africa. The version of the virus that infects chimpanzees, known as the simian immunodeficiency virus, is thought to have been passed to humans when they came into contact with infected chimpanzee blood during hunting. Despite transferring from chimpanzees to humans in the late 1800s, the virus did not exist in the United States until the late 1970s.

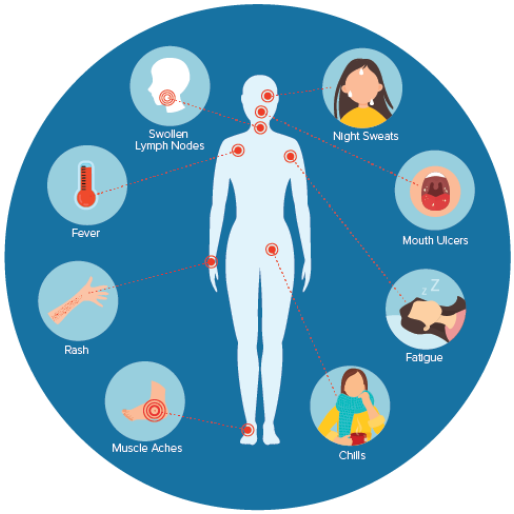
HIV works by infecting the body's T - helper (or CD4) cells, which are a type of white blood cell which helps to fight off infections. HIV fuses to these CD4 cells, taking control of the DNA to make copies of itself within the cell. This allows the HIV virus to reproduce and release more of itself into the bloodstream. This continued multiplication and spread is representative of a process known as the HIV life cycle. The HIV virus can be seen in the figure to the right, it uses MHC proteins to bind to the T-helper cells and create copies of itself to release more HIV and speed up the process of infecting the body. Drugs that are made to stop the spread of HIV can be used to target different stages in the HIV life cycle, so it is vital to know which stages a patient is in to treat them effectively.



Once in the United States, HIV cases quickly exploded. After being found in 1981, by 1985 every region of the world had reported at least one case of AIDS, with 20,303 total cases. By the end of 1990, there were over 307,000 AIDS cases and between 8 and 10 million people living with HIV throughout the world. In 1999, AIDS was announced as the number one cause of

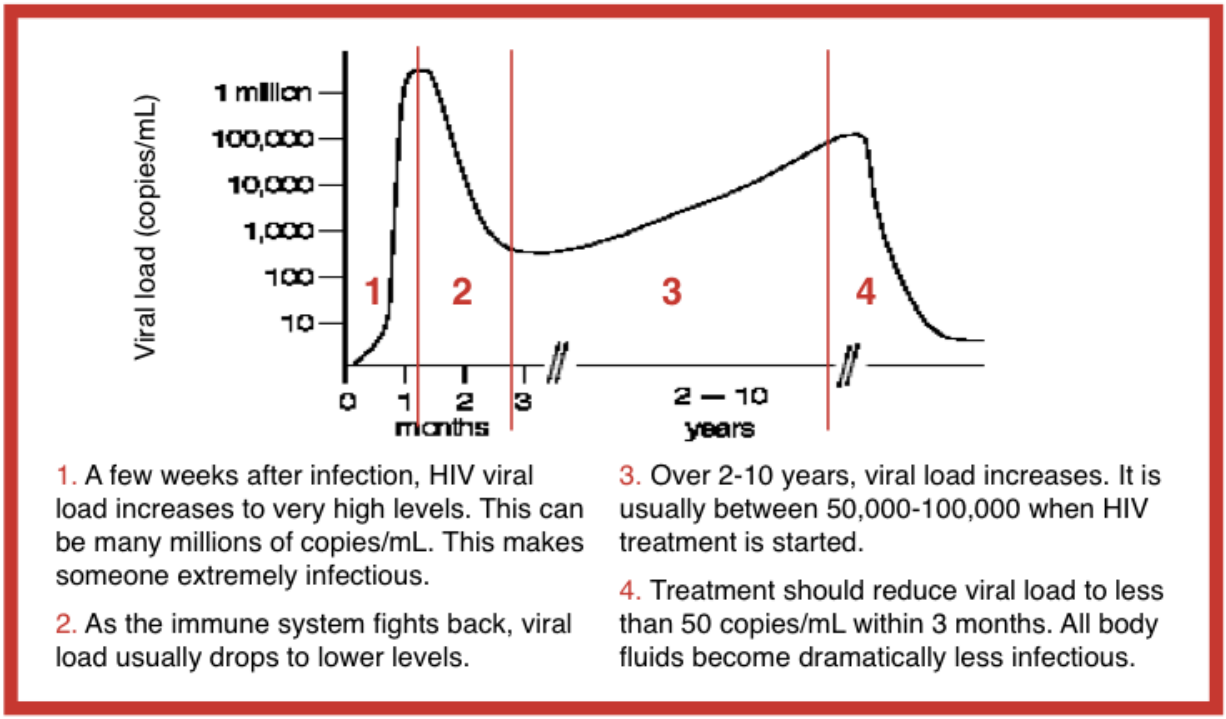
death in Africa and the fourth leading killer worldwide. Since its origin, an estimated 80 million people have been infected with HIV and around 36 million people have died worldwide.

HIV symptoms come in three main stages, with various symptoms associated with each. The first stage is known as acute HIV infection, where symptoms usually take two to four weeks to take effect, if at all. These symptoms are usually similar to flu symptoms, such as fever, headaches, sore throat, excessive fatigue, chills, muscle pain, swollen glands, or maculopapular truncal rash. The second stage is chronic HIV, which can last for up to 10 to 15 years. Symptoms of chronic HIV can vary in severity, most commonly presenting in the form of coughing or breathing difficulties, weight loss, diarrhea, fatigue, and high fever. The final stage of HIV is Acquired Immunodeficiency Syndrome, or AIDS, which can be identified by severe symptoms and a typical survival time of about three years. AIDS symptoms are usually severe chills at night, sweats, white spots and ulcers in the mouth, persistent high fevers, severe fatigue, genital or anal sores, rashes, regular coughing and breathing problems, significant weight loss, and persistent headaches.



When talking about diseases an important metric to consider is the viral load. The viral load of a disease is basically the go-to metric of how much of the disease is in your bloodstream, typically measured in virus particles per milliliter. As indicated by Figure 4, the viral load without treatment can vary depending on the timeframe. Typically from 2-10 years is when the treatment is started. This is such a wide window because many people as much as 13% of the population that already have HIV do not know it and need testing. As previously mentioned in

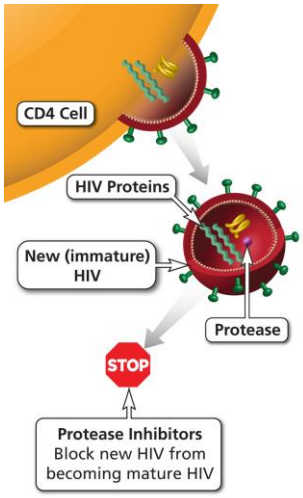
this paper, HIV has no miracle cure. In fact, there is no cure at all. Treatment helps manage the viral load to undetectable levels, which is around 50 particles per milliliter according to the chart.



III. Treatment History: A Timeline

As previously discussed, it is widely believed that HIV transferred from chimpanzees to humans in Africa as early as the late 1800s. Nearly 100 years later, in June of 1981, the first official reporting of HIV/ AIDS in the United States occurred. In December of 1982, there were reports of HIV cases from blood transfusions. From 1985 to 1989 there were a few key moments in the history of HIV. The CDC began issuing tests for the nation's blood supply, public outreach and information campaigns began to grow, the first HIV tests were approved, and Retrovir, the first nucleoside reverse transcriptase inhibitor (NRTI) was approved.

1995 began a new era for HIV treatments. Invirase (saquinavir), the first protease inhibitor was approved. Protease inhibitors went on to lead the field of HIV treatments for many years. Following this big release, in 1997, Combivir (zidovudine/lamivudine), the first NRTI combination tablet, was approved. Beginning in April of 1998, the CDC issued guidelines for the use of antiviral therapies for the treatment of HIV. In 2000, Kaletra (lopinavir/ritonavir), the first boosted protease inhibitor in a single tablet, was approved. Beginning in January of 2005, the CDC started to release recommendations of ways to prevent the spread of HIV and continued into 2006 by releasing new HIV testing regulations nationwide.

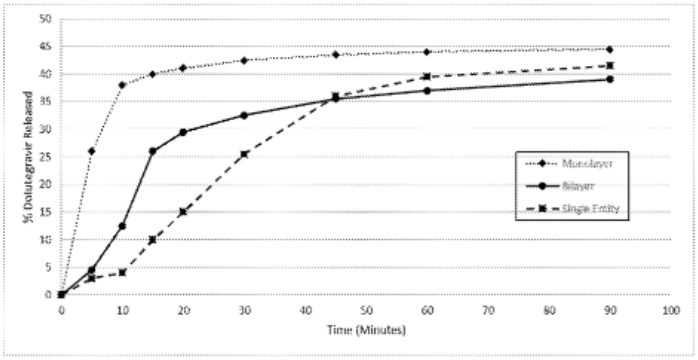


Along with these new testing options, Atripla (efavirenz/tenofovir/emtricitabine), the first once-daily HIV single-tablet regimen, was approved in 2006. The following year, the first integrase inhibitor, Isentress (raltegravir), was approved. The first oral entry inhibitor, Selzentry (maraviroc), was also approved. After a few years of little CDC interaction, in July of 2011, their

studies into TDF2s and Partner PrEP provided the first evidence that a daily oral dose of antiretroviral drugs used to treat HIV infection could also reduce HIV acquisition. In 2017, Juluca, the first two-drug single-dose treatment for those who were already on antiretroviral treatment was approved.

Following this breakthrough, on April 8th of 2019, the FDA approved Dovato, a two-drug single-dose treatment for patients not on antiretroviral treatment. Dovato was approved after 2 identical clinical trials with 1,433 patients. In the studies, 91% of patients who took Dovato had no detectable levels of HIV after 48 weeks. There is no cure for HIV, only drugs that can keep it under control so that it is no longer “detectable”. ViiV, the company behind Dovato holds 2 U.S. and 135 international patents for the drug. The US molecule patent expires in 2027 and the US crystal form patent expires in 2029.

Figure 1 Dissolution of dolutegravir



IV. Dovato - A Comprehensive Analysis

Pricing

As is the case with many prescription pharmaceuticals, pricing has been an important part of Dovato's life cycle. Dovato's two biggest competitors have been Biktarvy, and its sister drug, Juluca. Biktarvy, owned by competitor Gilead Pharmaceuticals, costs an average of $3,214 per month, or 38,568. Juluca, owned by ViiV, costs about $3,123 per month, or around $37,476 per year. Comparatively, Dovato is relatively cheap, only costing patients around $2,295 per month (30 tablets), or about $27,520 per year. The lowest GoodRx prices for both Dovato and Biktarvy was a discount of about 22% off the average retail price of each. Dovato is also covered by 100% of Medicare plans, as well as level 5 prescription drug plans, making patient access to treatment relatively easy. The deductible copay range for both Medicare and private insurance is around $80-$88. Outside of the United States, Dovato's prices are far more reasonable, with a cost that is less than half the price in the U.S., Canadian citizens only pay about $1,100 per month for the same dosage. Overall, competition for the treatment is not too competitive, with one of Dovato's largest competitors, Juluca, being created by the same company that makes Dovato in partnership with Janssen Pharmaceutical. Besides Juluca, Biktarvy does have a market majority for now, but due to Dovato's lower price and increased effectiveness, it should not be long for ViiV to overtake Gilead as the leader in HIV treatment.

Dovato as an Innovation

Dovato is the first treatment that allowed all HIV patients to take an effective treatment, as they did not have to be on antiretroviral treatment already. Dovato works by combining Lamivudine, a nucleoside reverse transcriptase inhibitor (NRTI), and Dolutegravir, an integrase inhibitor to decrease the overall load of HIV in your body to enable a patient's immune system to function properly. This combination has been proven to be able to, after 42 weeks, lower the concentration of the HIV virus in patients' bodies to undetectable levels, lowering their chances of complications and disease and improving overall quality and length of life as a result. Dovato is a treatment, not a cure, but it can keep HIV under control to a level of undetectability. When HIV is undetectable, it cannot be transmitted sexually. However, patients must continue to take their medication to keep enough inhibitors in their system. If they do not adhere to their dosage (a once-daily tablet, taken orally), they may face a series of side effects. These side effects include skin rash, blistering, peeling of the skin, muscle/ joint pain, fever/ chills, liver injury, dizziness, headaches, diarrhea, and anxiousness. Dovato is the first medication to combine just 2 medicines (Lamivudine and Dolutegravir) into 1 pill, drastically decreasing side effects and complications with prescriptions. In clinical studies, Dovato has shown to be just as effective as a 3 drug regimen. (Dovato is just one pill a day, that's it) (Similar to the difference between Sovaldi and Harvoni). Biktarvy is a 3-drug regimen vs dovato is 2, so both are one pill but dovato has been shown to lead to fewer side effects.

	DOVATO	A 3-Drug Regimen†
Headache	3%	4%
Nausea	2%	5%
Diarrhea	2%	3%
Trouble sleeping	2%	3%
Tiredness	2%	2%
Anxiety	2%	1%
Dizziness	1%	2%

V. QALY Analysis

Quality-adjusted life-years is a useful metric in healthcare statistics. The formula is as follows, Years of life * Utility = QALY. Here years of life represent how long you have left to live. Utility represents the current state of one's health. If someone is in perfect health, their utility is 1.0. If someone is in "half perfect health" their utility is 0.5. Researchers at Stanford University used mathematical modeling and a simulation to obtain some of these numbers. Their simulation had 2.5 million people in the age range of 15-59. They included some additional data that made predictions more realistic. This included simulating drug use, particularly 1.2 percent of the population along with a 6.5 percent chance of having HIV in this group. The purpose of this project was to see the change in QALY if people were screened for HIV more frequently. Two data points they used were annual testing, and once every 6 months. They found that the 6-month data set gained an additional 286 QALYs over a 20 year period. This research is very useful to the healthcare community because it can show them how to best improve their system. Finally, it is worth noting the realities of QALY in today's world. When HIV first came around in the 1980's people would develop AIDS in 10 years and then only have 1-2 years left to live at best. Nowadays, if a healthy 20-year-old gets tested and finds out they have HIV, then they can take medication and have a life expectancy of 70 years.

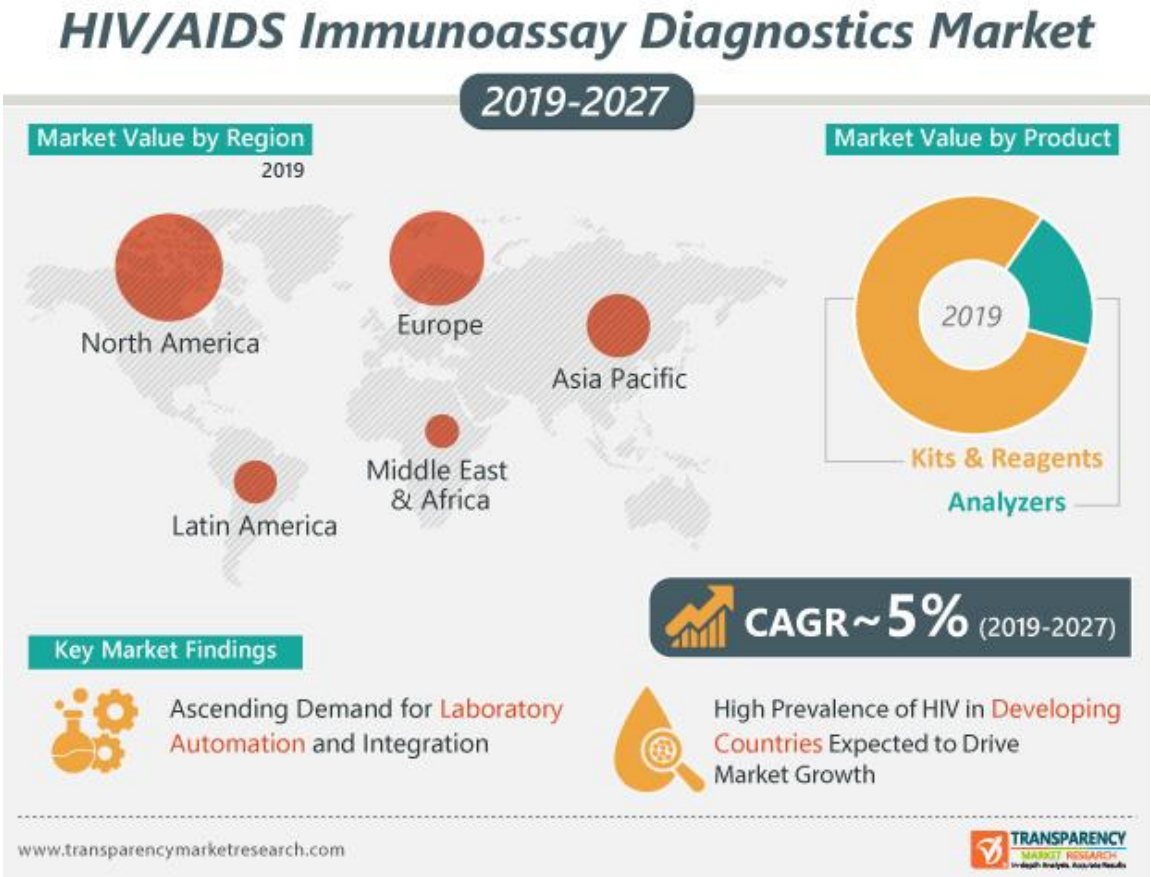
VI. Policy Implications

Dovato with Medicare

The price tag of a drug can seem sometimes irrelevant if the patient pool is small. A one million dollar drug for one person is a lot cheaper than a ten thousand dollar drug for half a million people. As previously mentioned, HIV was discovered in the early 1980s. In the beginning, many people were contracting the virus. Obviously, awareness was low and there were no good drugs to take care of the virus. Since then the human population has skyrocketed. Since the 1980's approximately 76 million people have been infected with HIV. About 38 million of that 76 million are still alive today. In 2020 alone 1.5 million people were diagnosed with HIV. The reason "diagnosed" is used is because people must get tested to know they have it. Many people, as much as 16% worldwide, do not know they have it. Keep in mind that everyone that has HIV or gets tested for it, is not going to be treated for it. Another key fact to consider is that the United States market is very different from the global market, especially when it comes to healthcare. With that out of the way, we are now ready to introduce the global market for HIV. With the 38 million people living with HIV today, the global market cap for HIV is around 31 billion dollars. Obviously, not everyone that has HIV is getting treatment. Even if everyone got treatment there is still the discrepancy of what they pay. Typically North America and European countries are going to be paying the most. The graph above shows a

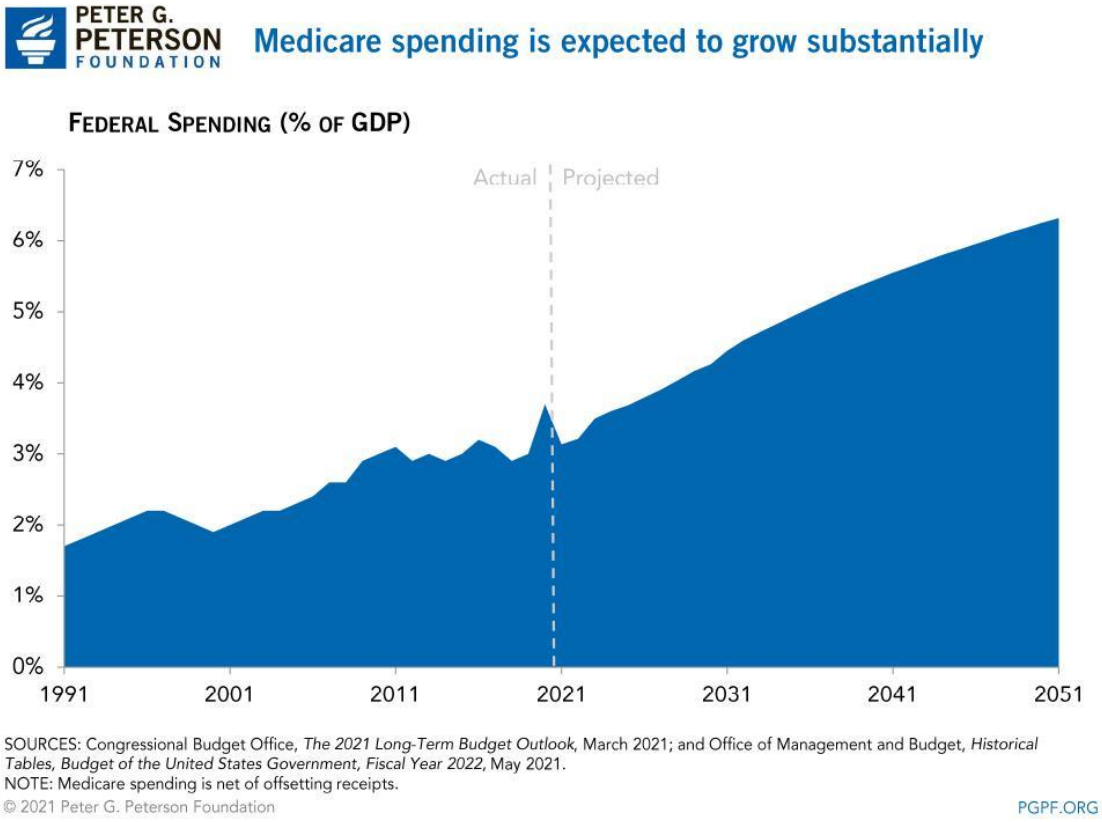
visual approximation of how much HIV is detected on each continent. North America hosts the largest patient pool, followed by Europe. This is likely to do with the number of developed countries on each of these continents. As previously mentioned, getting tested is a very important step that many overlook. In less developed countries there is likely a lack of testing and a lack of awareness to get tested. Therefore these countries may be underrepresented. Next, we must look at how much of this market cap belongs to the United States.

The United States is the prime spot for healthcare companies because here they can charge vast amounts of money for their products. In the United States, there are 1.2 million people living with HIV. Earlier we saw some prices for Dovato. The most prominent price was



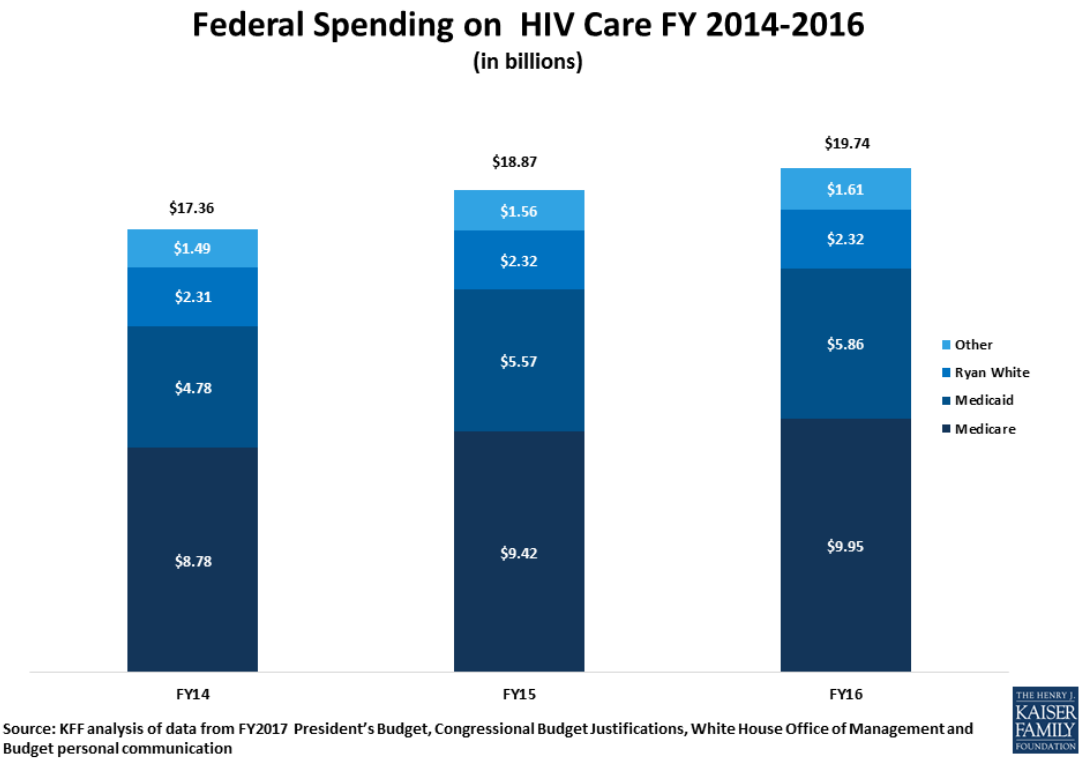
$27,520 a year. Doing some rather simple math we see that the maximum market potential for HIV in the United States is $33 billion. This is easily overstated. First off not everyone that has

HIV is getting treatment. There are those who are undiagnosed and completely unaware. Bringing it back to Dovato, in the first half of 2020, Dovato, and its sister drug Juluca, which is also manufactured by ViiV, brought in $476 million in sales. Not all of this revenue is coming directly from the consumer. In the United States, there is this little thing called Medicare.



Medicare for HIV

This graph shows a quick glance at some somewhat recent data on the healthcare industry spending. To put these numbers in perspective, the overall budget for Medicare in 2016 was roughly $685 billion. This means the HIV percentage of the Medicare budget in 2016 was roughly one percent. As the trend shows, US healthcare spending has steadily increased over the years. This is due to a number of reasons. The first being an increasing patient pool. Overall, the human population is increasing. When talking about an increasing patient pool one must also



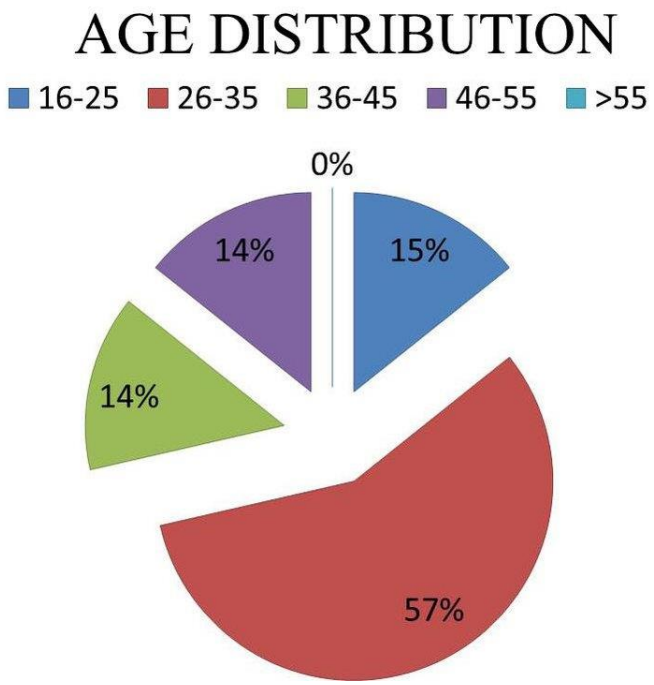
consider the existing pool and how large it stays. There is no cure for HIV, so the current population taking treatment this year must also take treatment the next year. In addition, modern

medicine is giving people longer lifespans. This also contributes to the existing pool remaining quite large year to year. Finally, there is the Affordable Care Act of 2010, or as it is commonly known as Obama Care. Simply put this enabled a larger portion of people in the United States to be eligible for healthcare coverage, and a larger demand beckons a larger supply.

As we will soon see, the majority of HIV patients are younger. Now, one might ask themselves, “isn’t Medicare for older people”? This is true, however, it is also true that Medicare covers long-term/permanent disabilities. This is where the younger population comes in. They typically receive Social Security Disability Insurance. After a two-year waiting period, they are then entitled to Medicare coverage.

Distribution

Speaking of ages, the testing pool for HIV goes lower than one may think. Based on the chart the lowest age distribution is from 16-25, but testing can start in the early teens. The primary age group that is affected is the 26-35 range. This is no coincidence, and its causes link into another interesting detail about HIV distribution. There are a few groups of people that HIV disproportionately affects. This includes racial minorities, gay men, bisexual men, and other men who have sex with men. Now it makes sense that the younger population is affected more because they are the ones having more sex, and of course, sex is the biggest transmitter, specifically male to male sex. In fact in recent years male to male sex accounts for 69% of new HIV diagnoses in the United States. This in no way means that male-to-male sex is the only way to transmit the disease. Heterosexual men account for 7% of the new diagnoses and heterosexual women account for 16%. Besides sexual contact, another big contributor to transmitting the disease is through needles. Addicts who do not want to spend money to buy fresh needles will share their needles with others. This accounts for another 7% of HIV diagnoses in the US.



VII. Conclusion

When considering breakthrough medical technologies of the past decade a few come to mind. Whether it be targeted cancer therapies, artificial organs, or even bionic prosthetics, they all have one thing in common. That they break the mold of traditional treatments and make a significant advancement in their treatment category. In recent years, HIV treatments have undergone a multitude of these "breakthrough" treatments, with the most recent being Dovato. Seeing the progress that has been made from 30, 20, or even 10 years ago gives me a lot of hope as to the advancements of medicine in the near future. Despite these great advancements in technology, our research has shown us one thing about preventing the spread of HIV, and that is

the importance of testing. By making testing a regular and common practice, we will see a significant decrease in the spread of cases for HIV, or any similar disease for that matter.

When it comes to "blockbuster" drugs they tend to follow a similar path. We usually see patent "thickets" to stop new entrants into the field, low competition, to allow for high pricing, and a treatment that does not cure a disease but instead makes life-long patients. It is very hard to predict these blockbusters, however, I believe that Dovato has the ability to become quite profitable for ViiV based on these criteria. Dovato is a treatment to make life with HIV better and longer, however, as it does not cure the virus, patients will have to take it for the remainder of their lives. Along with this, the relatively low number of true competitors, collection of over 100 patents worldwide, and the high price of the drug should allow ViiV to generate big profits. Much like the Humira's or Harvoni's of the past, Dovato utilizes these business strategies and market inefficiencies to create huge revenues from this life-saving drug.

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