
THE AIDS ACTION BULLETIN

▼ "IF ANYTHING IS SACRED THE HUMAN BODY IS SACRED." — WALT WHITMAN ▼

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THE NEWSLETTER OF AIDS ACTION BALTIMORE, INC.

FALL 2014

AAB DRUG PRICING UPDATE

FAIR PRICING COALITION UPDATE

By LYNDA DEE

AIDS Action Baltimore (AAB) has been a prominent member of the Fair Pricing Coalition (FPC) since it was founded by Martin Delaney and Linda Grinberg in 1999. I have been acting FPC chair since Martin Delaney died in 2009 and am now the FPC co-chair. Murray Penner from the National Alliance of State and Territorial AIDS Directors (NASTAD) is also a co-chair.

The FPC is a national coalition of activists who work on HIV and Hepatitis C (HCV) drug pricing issues and negotiate new drugs prices with HIV drug companies. We badger companies about drug price increases and ensure that they make their anti HIV and HCV drugs available to those who cannot afford them either through co-pay programs for people with insufficient insurance coverage or patient assistance programs for people with no insurance. We also work the AIDS Crisis Task Force to ensure that Ryan White AIDS Drug Assistance Programs (ADAPs) that provide access to prescriptions for the working poor across the nation receive generous rebates for all drugs purchased for people with HIV. Our work helps to control drug costs, thereby ensuring access for recipients of state ADAPs, Medicare, and Medicaid, as well as those who are privately insured, underinsured and uninsured. This type of advocacy does not happen in any other disease field.

We have worked very hard for many years to ensure generous uniform industry patient assistance programs (PAPs) for people with HIV and HCV who do not have insurance. The FPC has advocated for an income eligibility criteria of 500% of the federal poverty level (FPL) for people with HIV, (\$58,350 for individuals in 2014), and over \$100,000 for more expensive HCV drugs. All but one HIV drug company uses the 500% FPL criteria for HIV PAPs. Janssen's PAP criteria is 200% of the FPL, but they will make exceptions for people whose income is over their 200% cap. HCV drug manufacturers Gilead and Vertex use the over \$100,000 annual income for individuals for their HCV PAPs. The criteria for Janssen's and Merck's HCV PAPs is 500% of the FPL. You can find more PAP contact and eligibility information at: <http://fairpricingcoalition.org/projects/>.

Current company co-pay programs are a direct result of several years of intense work and negotiations between the FPC and representatives of the pharmaceutical industry. We almost lost our co-pay programs last year after a complicated government snafu. The community convinced former Secretary of Health and Human Services Kathleen Sebelius to rule that the Affordable Care Act (ACA) was not a "government program" for co-pays purposes in order to avoid federal prohibitions that do not permit co-pay programs for people in government programs. We feared that all our work in this arena would come to a screeching halt when the Centers for Medicare and Medicaid Services (CMS) issued an unclear ruling thereafter, indicating that co-pay programs were not favored and/or permissible for ACA patients, and also confused the co-pay playing field for Ryan White covered patients. The underlying issue is this. Both government and private insurance payers do not favor co-pay programs because they are seen as inducements for people to purchase more expensive brand name drugs when cheaper generic versions are available. While the drugs may be cheaper for the patient, the brand name drugs cost are much more expensive for the entity that has to foot the bill. This problem does not usually even apply to HIV and HCV because most of our drugs are still under patent protection which means there are no generic alternatives.

Some companies continued their co-pay programs after the CMS ruling, but some did not for fear of being sued by CMS. The landscape was confused to say the least. But the FPC finally convinced all HIV and HCV drug companies to keep their co-pay programs alive based on the Sebelius ruling. We were eventually successful after a long slog. Now very generous co-pay programs are in place for all anti-HIV and HCV drugs for people whose medical expenses are not covered by Medicare and Medicaid.

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A Drug by Any Other Name

The basics of generic medications, bioequivalence, and the push for good manufacturing practices

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Note from the President

This issue is devoted to AAB's advocacy work with the Fair Pricing Coalition (FPC) with respect to drug pricing and access to prescription drugs from HIV drug co-pay and patient assistance programs. AAB has been working with the FPC since it was founded by Martin Delaney and Linda Grinberg in 1999. I have been acting chair since Martin Delaney died in 2009 and am now the FPC co-chair. Murray Penner from the National Alliance of State and Territorial AIDS Directors (NASTAD) is our other co-chair.

The FPC negotiates new drugs prices with HIV drug companies, badgers them about drug price increases and ensures that they makes their antiretroviral drugs (ARVs) available to those who cannot afford them either through co-pay programs for people with insufficient insurance coverage or patient assistance programs for people with no insurance. We also work with the AIDS Crisis Task Force to ensure that AIDS Drug Assistance Programs (ADAPs) that ensure access to prescriptions for the working poor across the nation receive generous rebates for all drugs purchased for people with HIV. This type of advocacy does not happen in any other disease field.

As drugs for HIV and HCV become more expensive, this type of advocacy is more necessary than ever. I hope you will enjoy reading about this work and will share the access program information with your friends. We need to get the word out to people that these programs are available. We need your help to let people know about what programs are available to help defray the cost of really expensive ARV medications.

We are also including links to the recent International AIDS Conference Towards a "Cure" Workshop that was held in Melbourne, Australia on July 19-29, 2014 as well as "Cure" research from 2014. AAB is also intricately involved with HIV "Cure" research. There are six community members on the International Martin Delaney Collaboratory (MDC) Community Advisory Board (CAB). Each of the three MDCs have two community representatives who serve on the International MDC CAB. The work of the MDCs is strictly devoted to HIV "Cure" research. Jeff Taylor of San Diego and I are co-coordinators of the CARE Collaboratory CAB and two of the members of the International MDC CAB.

Let me take this opportunity to thank all of our loyal supporters who attended our recent benefit at Brookside on September 21, 2014. We raised over \$45,000 and I think you will agree that a fabulous time was had by all. Angie and Blake Cordish who opened their lovely home to us again this year deserve special thanks. We are so grateful to them for their generous support.

It's that time of year again. Please remember AIDS Action Baltimore when making your holiday donations. You can read why we still need your help as well as the different types of work we are doing by clicking on the link to our Fall Direct Mail Appeal Letter. <http://www.aidsactionbaltimore.org/> Remember without the help of people like you, there would be no AIDS Action Baltimore.

Lynda Dee
President



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Detailed contact and eligibility information on HIV and HCV drug company co-pay programs can be found on the FPC's web site. <http://fairpricingcoalition.org/projects/>. As drugs for HIV and HCV become more expensive, PAP and co-pay program advocacy is more necessary than ever. Please share this access program information with your friends. We need to get the word out to people that these programs are available. We need your help to let people know about free drug PAPs for people without insurance and co-pay programs that help defray the cost of really expensive ARV medications for people with insurance.

We have also convinced most major HIV and HCV drug companies to make generous contributions to non-profit groups like the Patient Access Network Foundation (PAN) so that co-pay benefits will also be available to Medicare and Medicaid patients. PAN HIV program co-pay information can be found at: <http://www.panfoundation.org/hiv-aids>. PAN HCV co-pay information can be found at: <http://www.panfoundation.org/hepatitis-c>.

Now that we have ironed out the "government program" co-pay snag, we are concentrating on co-pay costs as well as all out of pocket (OOP) costs occasioned by other costs levied by insurance companies after enactment of the ACA. For many years, the FPC concentrated heavily on advocacy for programs like ADAPs which covered prescription costs for the working poor. Because of onerous OOPs that so many people cannot afford, the FPC has now expanded its focus largely to ACA network clients and private insurance clients. The FPC is currently working to ensure that all HIV and HCV drug companies cover at least \$6,350 annually for all prescription OOPS, including co-pays, deductibles and co-insurance costs. So far, we are about half way there. We are also trying to convince HIV drug companies to institute a price increase freeze. The increases in the price of HIV drugs since approval are unbelievable. As you can see, every year our work gets tougher and more complicated. There is always more to do to ensure that people actually have access to the drugs we worked so hard to get approved by the FDA. For more information on the work of the FPC as well as many facts and figures related to pricing challenges, including the percentage of price increases for HIV drugs since FDA approval, check out a recent presentation I made at a meeting of the Federal AIDS Policy Partnership in DC.

<http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/12/FAPP.pdf>.

The FPC has also been inundated with work surrounding the launch of new drugs which can actually cure HCV without the devastating side effects caused by older HCV drugs, namely interferon and ribavirin. Many people with HIV are also co-infected with HCV. This is especially true in the Baltimore metropolitan area. Most of the major HIV drug companies also have new HCV drugs, called Direct Acting Antivirals (DAAs). The new DAAs were supposed to usher in a new

day for people with HCV. The HCV community worked very hard to ensure that HCV testing would be covered by advocating with the US Preventive Services Task Force (USPSTF) to give HCV testing the grade necessary to ensure that insurance companies will pay for HCV testing. The USPSTF has a history of waiting inordinately long periods of time to give their imprimatur to many tests and vaccines. It was a major undertaking to move this often out of touch body into the 21st Century in this regard.

HCV testing will now be reimbursed. Hundreds of thousands of people who were never able to obtain and/or afford health insurance would now be able to access these amazing new DAAs as a result of the ACA. The new DAAs have amazing 90 to 100% cure rates with much shorter courses of therapy. Some DDA regimens cure HCV in 12 weeks, instead of having to take old 48 week interferon containing regimens with horrible side-effects and often abysmal cure rates for more advanced patients and patients with the most prevalent and hard to treat genotype (GT) HCV GT 1a.

Hurrah, right! Not quite... Gilead Sciences' pricing of Sovaldi, its highly effective new HCV drug is unconscionable, resulting in wide-spread onerous national prior authorization requirements and restrictions from both public and private payers.

Sovaldi is arguable the most effective new HCV DAA, and also requires the shortest treatment duration. Sovaldi was first approved by the FDA in December of 2013 for use with interferon and ribavirin and priced at an exorbitant price of \$84,000 for a 12 week regimen or \$1,000 per pill. The price of Sovaldi has sparked unprecedented outrage from all quarters, resulting in Congressional investigations in both the Senate and the House of Representatives, suits against Gilead and relentless unfavorable press and public relations. In all my years with the FPC, I have never seen such furor over any one drug price. Nevertheless, Gilead's Sovaldi launch has been the most successful in the history of drug marketing. Gilead has realized over 8.5 BILLION dollars in Sovaldi sales in the first three quarters of 2014 alone. When is enough, enough? Here's what the FPC thinks of the price of Solvaldi: <http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/12/Sovaldi.pdf>.

Gilead's newest HCV drug Harvoni is what is known as a fixed dose combination (FDC) or single tablet regimen (STR). This means there is more than one drug in one pill, like Gilead's HIV four drugs in one pill FDC Stribild which was also priced astronomically. <http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/12/Stribild.pdf>.

Gilead's Harvoni was approved on October 10, 2014 and is the first one pill once a day, interferon/ribavirin free, 12 week treatment for most HCV genotypes. The Congressional investigations, law suits and endless bad press Gilead has experienced since Sovaldi was approved seems to be hitting home. Harvoni was priced at \$94,500 for 12 weeks of treatment.

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While this price is still an unsustainable budget buster, especially for many federal programs with limited resources, it is less than the \$100,000+ price tag forecasters were predicting. Later stage patients with cirrhosis may need to take as much as 24 weeks of Harvoni with a price tag of \$189,000. Again, when is enough, enough? <http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/12/Harvoni.pdf>.

These outrageous prices have severely limited patient access to Sovaldi and Harvoni, especially for Medicaid patients who are, of course, the poorest of the poor. Medicaid coverage is dictated on a state by state basis. Many state Medic aids have placed prior authorization restrictions on Sovaldi and Harvoni, including requirements that only patients with HCV Stage F3 and F4 are eligible to access these expensive drugs and that prescriptions can only be written by certain specialists who are often inaccessible to many patients. These restrictions subject people to the very real potential of progressing to cirrhosis and liver cancer before they can access a life-saving regimen that can cure HCV. So much for the dream of a widely accessible cure for HCV.

The FPC will continue to beat on Gilead about the overpricing of its HIV and HCV drugs. We will also work with other drug companies with new HCV DAA regimens in order to spark competition with Gilead. AbbVie's 3D HCV regimen is due to be approved by the FDA no later than December of 2014. AbbVie has the chance to change this unfortunate dynamic. The FPC hopes that AbbVie will use this opportunity to reset the HCV payer landscape and price its new regimen in a manner that will result in a reversal of these horrible restrictions caused by the original price of Sovaldi and the subsequent price of Harvoni. We will continue to do this work until life-saving HCV drugs are widely available to people

HIV "Cure" and ARV Research

A AB is working with government, researchers, industry and community activists around the world on HIV "Cure" and ARV Research. The following links provide highlights on "Cure" and ARV Research from recent conferences.

<http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/04/AABHIGHLIGHTSFROMTHECROI2014.pdf>

<http://www.aidsactionbaltimore.org/wordpress/wp-content/uploads/2014/12/CUREWORKSHOP.pdf>

AAB GENERICS REPORT

A DRUG BY ANY OTHER NAME: The basics of generic medications, bioequivalence, and the push for good manufacturing practices

By TIM HORN

Securing access to generic drugs to treat HIV, hepatitis C virus (HCV), and tuberculosis (TB) is now one of the most prominent strategies of global health care and treatment activism.

In the vast majority of low-income countries, the licensing of generic antiretrovirals (ARVs) is a key driver behind the 40-fold increase in treatment access for people living with HIV since 2002. In high-income countries, particularly the United States, a confluence of skyrocketing brand-name (originator) drug costs and the approaching expiration of patents protecting several commonly used ARVs has led to a tremendous interest in the potential cost savings and acceptability of HIV treatment regimens with generic components.

Effective responses to the entrenched TB epidemics are also dependent on affordable and consistent access to generic antimicrobial agents. Moreover, with the arrival of short-course, all-oral curative—but expensive—therapy for HCV, there is mounting interest in generic equivalents to new originator drugs to ensure that all those who need these lifesaving therapies, no matter where they are in the world, have affordable access to them.

The ongoing development, regulatory approval, and evaluation of generic drugs are dependent on activism. This requires a basic understanding of the science and policies of generics, particularly the practices that must be followed to help ensure equivalence and quality control.

The World Health Organization defines a generic drug as a "pharmaceutical product, usually intended to be interchangeable with an [originator] product, that is manufactured without a license from the [originator] company and marketed after the expiry date of the patent or other exclusive rights." This is mostly accurate, though generic versions of patent-protected originator ARVs have been produced through voluntary or compulsory licensing pathways (and in countries where international patents are not recognized, particularly for older HIV

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drugs), with similar approaches being eyed for HCV and TB drugs as well.

For many generic drugs, particularly oral and injectable medications that work systemically, establishing equivalence to innovator products is a fairly straightforward process. First and foremost, a generic drug must contain the same active pharmaceutical ingredient (API). It must involve the same route of administration (e.g., oral), formulation (e.g., capsule or tablet) and dosing. It must also meet stringent criteria for bioequivalence—the extent (and, often, the rate) of absorption must not differ significantly from that of the originator drug. A generic drug that meets these standards should not behave any differently, either in terms of efficacy or safety outcomes. (Medications that work topically or locally, such as ointments or ophthalmology drugs, and biologics that use active substances derived from living sources such as cells, including interferons and monoclonal antibodies, must meet other criteria to prove equivalence.)

Bioequivalence is assessed in studies, often involving 20 to 50 human volunteers without the infection for which the drug is indicated, and requires comparing a series of blood samples collected in the minutes, hours, and days after sequentially administering single doses of the originator and generic drugs. Of greatest interest to generics manufacturers and regulatory agencies, such as the FDA, are two measures of bioequivalence: the maximum concentration of the drug (C_{max}) and the total extent of drug absorption (the area under the curve, or AUC).

To be considered bioequivalent, a generic drug's C_{max} and AUC do not need to exactly match that of the innovator drug. While some sources note that the FDA only requires the extent of a generic drug's concentration (C_{max} and AUC) to be within 80 to 125% of that established for the innovator drug—a difference of 45%—this is something of an oversimplification. More accurately, the 90% confidence intervals for the ratio of the C_{max} and AUC mean averages must be in this range. In fact, according to a meta-analysis published in 2009, a review of more than 2,000 studies conducted between 1996 and 2007 found that the average difference in bioequivalence between generic and innovator drugs was 3.5%.

Establishing that the API of a generic drug is bioequivalent to that of the originator drug does not necessarily mean that the medications are exactly the same. For example, a generic tablet may be a different size, shape, or color than the originator product. The U.S. Food and Drug Administration (FDA) also does not require that generic drugs contain the same inactive ingredients (excipients), such as binding materials, flavoring agents, dyes, and preservatives. In effect, it is possible that someone may experience a side effect upon switching from an originator drug to a generic drug, such as an adverse reaction to a particular excipient.

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Thank You . . .

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Despite these differences, generics have been confirmed, in various studies, to be therapeutically equivalent to originator drugs. In a Harvard Medical School meta-analysis of 47 clinical trials of cardiovascular drugs, no statistically significant differences in efficacy or safety outcomes were documented among those receiving generic drugs compared with those receiving originator products. A study comparing generic and originator formulations of extended-release clarithromycin for respiratory tract infections also demonstrated similar outcomes. Additionally, comparable clinical outcomes were noted in a large Zambian cohort comparing generic and originator ARVs for HIV infection.

Most ARVs have a relatively wide therapeutic window. If taken correctly, blood concentrations of the drug remain safely above the minimum effective concentration required to be effective and below the minimum toxic concentration required for optimal safety (see figure). In turn, even if a generic ARV's absorption differs somewhat from that of the originator product, neither efficacy nor safety should be compromised. This is especially true with the standard practice of using regimens containing three or more ARVs to maximize efficacy. And while even a slight upward deviation in a generic ARV's absorption can potentially increase the risk of serious side effects, this was a much more significant problem with older drugs used to treat HIV (many of which are rarely used in the United States and are being phased out in low- and middle-income countries).

Another key approval requirement for generic drugs undergoing stringent regulatory approval, which includes generic versions of originator drugs to be made available in low-income countries through the President's Emergency Plan for AIDS Relief through the FDA tentative approval process, are current good manufacturing practices (GMPs). In short, all drug manufacturers must prove that they maintain appropriate facilities, equipment, and staffing, and that they follow strict procedures for producing medicines through every aspect of sterilization, development, testing, production, quality control, and distribution. GMP enforcement is a major bottleneck for regulatory agencies like the FDA and European Medicines Agency, as they require regular inspections of drug manufacturing facilities. This is a daunting task in light of the fact that the pharmaceutical supply chain has become increasingly globalized and involves numerous API and finished drug manufacturers in various countries, compounded by limited regulatory agency resources and staffing to rapidly and thoroughly conduct the necessary inspections in lockstep with the increasing number of new generic drug approval applications (ANDAs). A consequence of this bottleneck has been a 30-month backlog of the 800 to 900 ANDAs received annually—including those for drugs that have clearly established bioequivalence—which stymies competition among manufacturers required to drive down prices, drains regulatory agency resources, increases costs to generics manufacturers, and decreases patient and provider confidence in the quality of generic products.

In an effort to hasten the delivery of quality-assured generic drugs, the Generic Drug Users Fee Amendments (GDUFA) of

2012 were signed into law by President Obama on July 9, 2012. Comprising a mix of ANDA, backlog, and facility fees paid by API and finished drug manufacturing sites, the legislation provides the FDA with an influx of US\$1.5 billion through 2017 to improve the timeliness of generic drug application reviews. GDUFA also aims to enhance the FDA's ability to protect generic drug users—both domestically and globally—by requiring that U.S. and global manufacturers are held to consistent, high-quality standards and are inspected biennially, with comparable rigor and frequency.

GDUFA's fees are not, however, without significant concerns. Though they won't likely hinder manufacturer interest in high-prevalence diseases in the United States, particularly if streamlined FDA approval processes result in expedited revenue returns, the fees are potential barriers when it comes to low-prevalence diseases. Tuberculosis, and to some extent HIV, are prime cases in point. We need to encourage more generic drug manufacturers to seek regulatory approval, not only to ensure multiple sources of essential drugs and to prevent stock-outs, but also to maximize competition and drive down treatment costs. When it comes to low-prevalence diseases, the GDUFA fees forecast by manufacturers may mean even less returns on their investment. For TB programs in the U.S., this would not be a step in the right direction.

The FDA continues to chart its GDUFA implementation plans, including a public hearing that took place on September 17 and a comment period open until October 13. TAG has been actively engaged in these processes, along with several other domestic and global efforts to overcome research, regulatory, and licensing challenges that hinder access to safe, effective, and affordable generic drugs for HIV, HCV, and TB. ▼

In Memory of ...

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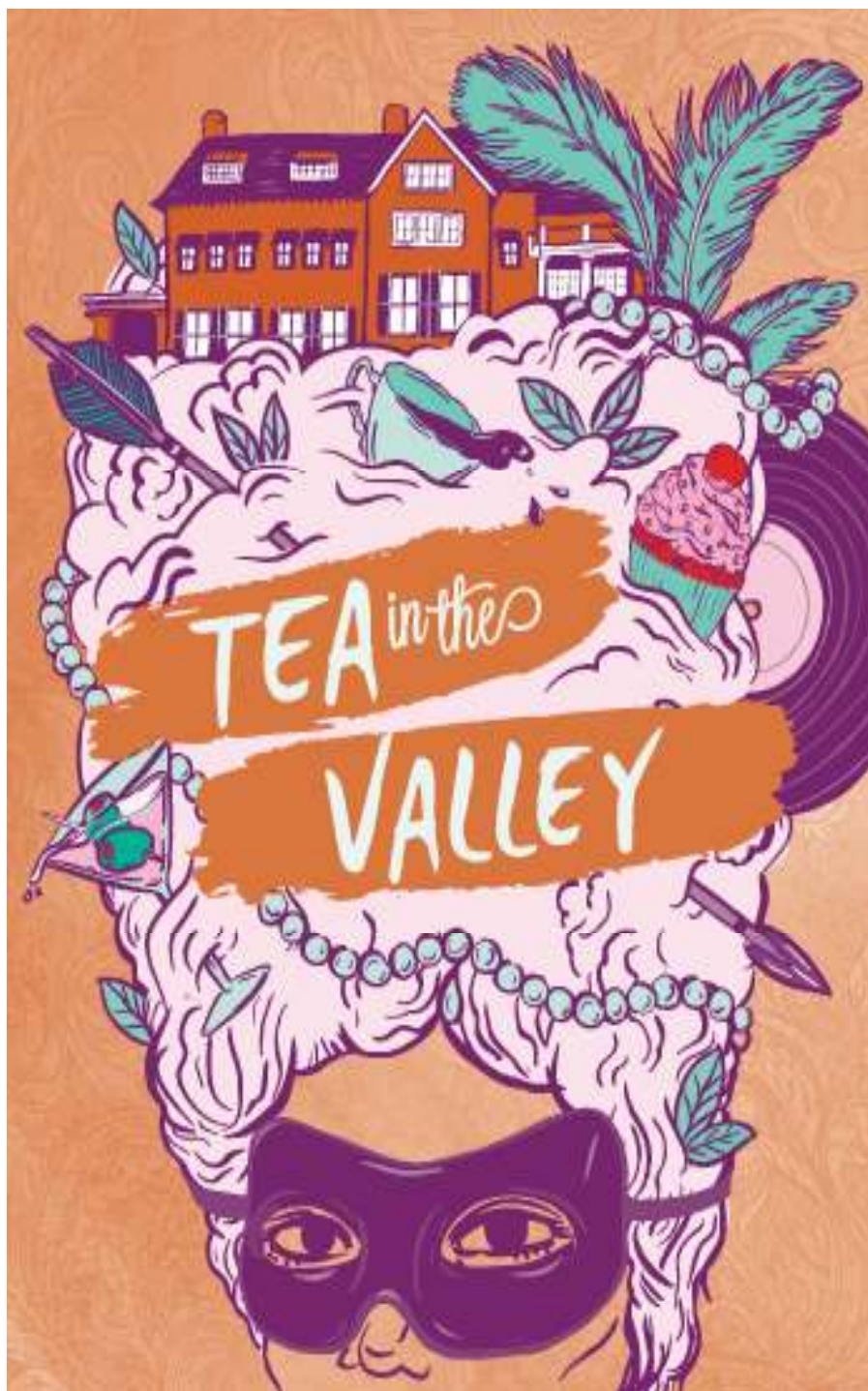
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Fair Pricing Coalition (FPC)

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