AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we are the patient voice."

March 20, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Public Comments - Maryland Prescription Drug Affordability Board Meeting, March 25, 2024

Dear Members of the Maryland Prescription Drug Affordability Board:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this drug affordability process. We hope the Board will consider these statements as you continue forward with your drug affordability program.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

On behalf of patients and care partners residing in Maryland, we thank the state for recognizing a need to address the high costs of prescription drugs and appreciate your dedication to ensuring patients will have adequate opportunity to provide input. As a group led by patients who represented 40 percent of those participating in the Colorado PDAB and CMS Listening Sessions for Enbrel and Stelara, we feel positioned to share lessons learned and request the opportunity to work with the Maryland PDAB and Stakeholder Council as you set up processes to ensure clear and meaningful participation.

Patient and Patient Organization Involvement in the Process. In follow-up to our January letter, we continue to urge the board to ensure that patients have opportunity for meaningful input into the affordability assessment. Not only should patients be invited to engage with board members and staff to provide input specific to drugs they are taking or could take in the future based on their chronic conditions, but the board should also work directly with patients on the mechanisms put in place for public input to ensure that the right questions are being asked and the right data is being collected. Collaboration with patients ensures the board truly identifies and addresses patient needs and can help prevent policies that could impede therapeutic access and stymie innovation.

To that end, we know that boards are looking at the steps and processes being utilized for drug reviews in other states. Based on discussions with staff, we know that the Colorado board is a specific point of reference. As such, we are enclosing feedback we recently provided to the Colorado board on their patient survey design, which we believe has led that board to some erroneous conclusions by that board. We hope this reference will aid the Maryland board in their own patient survey or patient input models.

Focus on Patient Outcomes. Furthermore, as the board refines its initial list of medications for further review, we encourage the board to keep at the forefront of their deliberations the vulnerable communities of patients that rely on each of those drugs to maintain their health. Chronic conditions can be incredibly debilitating and keep those diagnosed from maintaining normal functions and daily routines. Worsened health conditions can result in more frequent doctor visits, the need for invasive medical interventions, and hospitalizations. Patients who identify and maintain effective treatments can resume their normal lives. It cannot be understated that the medications subject to review are life-changing for the patients they treat. Therefore, we urge the committee to keep patient impact at the forefront of its deliberations.

Avoid Impeding Patient Access. Additionally, as the board reviews drug affordability, we would like to emphasize the importance of maintaining unrestricted access to broad treatment options for patients with complex conditions.

- Patients with complex and chronic conditions often spend years identifying treatments that work for them – it is typical for a patient to try and fail at multiple treatments before finding one that is most effective for them.
- Treatments can work for a specific patient for multiple years but then become less effective, forcing a change in therapies.
- Throughout a lifetime of maintaining a chronic disease, many patients will face switching medications multiple times as their selected treatment becomes less effective to them personally.
- Treatments that are classified as therapeutic alternatives are not guaranteed to work for every patient.

Therefore, health policies mustn't impede access to treatments or lead to fewer options for patients.

Prevent Unintended Consequences to Patients. Finally, focusing solely on the price of drugs ignores the many complicated factors that ultimately drive costs up for patients and oversimplifies a very complex process. Additionally, reviewing only a handful of medications can create further inequities, picking winners and losers among patients and patient populations. If access is impeded or utilization management increased, patients will suffer from unnecessary delays, fewer treatment options, and more barriers to accessing the life-changing care they need.

Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,
Tiffany Westrich-Robertson

Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

Chronic Disease Coalition

Maryland Prescription Drug Affordability Board
16900 Science Drive Suite 112-114
Bowie, MD 20715

March 15, 2024

Chair Debenedetto, members of the board,

On behalf of the Chronic Disease Coalition, thank you for the opportunity to provide our thoughts and feedback as the PDAB evaluates the affordability of various treatments for chronic conditions.

The Chronic Disease Coalition is a national nonprofit organization dedicated to raising the patient voice and perspective in healthcare policymaking. The coalition was founded in 2015 to advocate for people living with long-term or lifelong health conditions. Our patient advisors and partners represent common diseases (e.g., diabetes, kidney disease, arthritis), rare diseases (e.g., Guillain-Barré syndrome, hypoparathyroidism), and many other conditions whose scale and scope are still not understood.

With these written comments, we hope to highlight patients' critical need for consumer-level cost controls and continued innovation in medicine. Especially as the board contemplates upper payment limits, it is critical to recognize how limits affect the treatments and cures that patients depend on.

- To be clear, regardless of whether a chronic disease is rare or common, chronic disease patients are extremely cost-sensitive; we also recognize the state's interests in controlling costs. Those are not, however, interchangeable policy mechanisms.
- Chronic disease patients need more access to better treatments, and any action to address pricing must consider its potential impact on similar medications and the landscape of treatment development.
- Impacting the prices of a few life-saving drugs could inadvertently affect costs across other categories and slow the development of future treatments.
- All new treatments only come from the private sector, and the next generation of patients deserves the next generation of cures.

Additionally, while the PDAB rightfully considers manufacturer prices as a starting point for discussions on affordability, it's crucial to recognize that list prices don't reflect patient costs, and that there are other ways of protecting patients. Achieving meaningful progress requires a holistic approach that includes proven reforms directly benefiting patients. The CDC was proud to support a bipartisan bill that is moving through the Legislature in Annapolis this year — SB 1019 — PBM reform and benefits patients directly. By prioritizing reforms like these bills that offer immediate and tangible benefits to patients, we can collectively advance the cause of more accessible and effective healthcare.

Sincerely,

Nathaniel Brown
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COMMITTEE TO PROTECT
HEALTH CARE

March 20, 2024

Dear Members of the Maryland Prescription Drug Affordability Board,

The Committee to Protect Health Care writes to express our strong support for the establishment and work of the Maryland Prescription Drug Affordability Board (PDAB). As doctors and medical professionals committed to expanding access to affordable health care, we believe a strong PDAB will help patients better afford the prescription drugs they need to manage their health conditions, live, and thrive.

The Committee is proud to support the law that created a PDAB in Maryland. In other states, including Colorado, Illinois, Michigan, Minnesota, New Mexico, and Virginia, doctors mobilized to communicate about, and advocate for the passage of, similar PDAB legislation. That's because we know that a PDAB is one of the best tools states have to rein in the skyrocketing costs of prescription drugs for patients.

Your work is essential and deserves to begin without delay. Doctors are all too familiar with what happens when patients don't take the medications we've prescribed them due to cost. They deal with unnecessary pain and discomfort. Their health conditions, which are often manageable early on, worsen, becoming more difficult, expensive, and painful to treat.

On the other hand, we're also familiar with how access to prescription drugs can help keep patients healthy and manage their medical conditions. We see each and every day how, when patients take medications as prescribed, their quality of life improves and they're able to keep more serious complications at bay.

Because we see the important role access to medications can play in people's quality of life and overall health and wellbeing, we stand ready to support this PDAB and its work, from reining in costs for state and federal employees to expanding its scope in the near future so all Marylanders can benefit from lower drug costs.

To ensure that the PDAB is able to work and help lower costs for patients, we urge you to stand firm against pressure from the pharmaceutical industry. We urge you to begin empowering Maryland's PDAB to begin work without delay.

As you begin this important, potentially life-saving work, we also ask you to stand firm against the unsurprising onslaught of disinformation and big spending from Big Pharma, which has been fighting efforts to make prescription drugs more affordable so drug companies and CEOs can protect and pad their already hefty profits. When legislation to create Maryland's Prescription Drug Affordability Board passed, the drug industry retained more than 100

lobbyists — more than two for every state senator. The industry spent more than $1 million lobbying in Maryland. Representatives from PhRMA, the trade group representing pharmaceutical companies, tried to blame high drug costs on insurers and pharmacy benefit managers. They also baselessly and with no evidence claimed the Board would leave cancer patients without their treatments, among other scare tactics.

Let's be very clear: Too many patients in Maryland already can't afford the prescription drugs they need, and prescription drugs don't work when patients can't afford them. Right now, too many cannot. The status quo isn't working — we can't let Big Pharma maintain the status quo.

The Committee to Protect Health Care looks forward to supporting your work to hold pharmaceutical corporations accountable for their price-gouging, and to set upper payment limits on life-saving drugs so that patients can actually afford them. You have an opportunity to improve the health of countless people in Maryland and even build upon the protections of the PDAB so more Marylanders can get access to affordable prescription drugs.

Thank you.

Sincerely,

Dr. Rob Davidson

Executive Director

COMMUNITY ACCESS NATIONAL NETWORK

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Submitted for Public Comment: Maryland PDAB Meeting: March 25, 2024 Agenda Item: Public Comment, Cost Review Study

March 13, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

About CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

We write today, deeply concerned with the Board's suggestion to begin a "cost-review study" of the antiretroviral medications used for both treatment and prevention of HIV, Biktarvy. We wish to begin with recognizing that the naming a medication for "cost review study" does not necessarily indicate any final determination of "affordable" nor does it dictate any imposition of an "upper payment limit" or regulated rate setting by another name. However, we are concerned the Board lacks sufficient knowledge to make appropriate considerations regarding any antiretroviral, the public health programs served through 340B rebates, and the very carefully constructed fashion in which public health is funded. The long and short of our concern is imposing an arbitrary reimbursement rate will necessarily divest from health equity efforts and harm efforts to achieve certain public health goals. We will explain in detail below and are grateful for your time in reviewing the information provided.

340B Entities Will Be Negatively Impacted by a UPL

Concerns related to 340B previously voiced have not been sufficiently addressed. Similar to the misleading testimony offered by a witness to the Vermont Senate in February, those 340B Grantee entities discussing concerns with Board have been told the equivalent of "a UPL will not effect 340B". This is not true.

340B finds its value in rebates which ultimately reduce acquisition costs for certain covered entities after reimbursements have been made. Straight forwardly, a reduction in allowable reimbursement rates necessarily reduces the rebate value realized by these covered entities. An upper payment limit below current reimbursements, therefore, reduces the realized savings and revenues which may be reinvested into public health programs, particularly among federal grantees (including but not limited to the state's AIDS Drug Assistance Program - ADAPs, STI Clinic Grantees – 318 Grantees, and Federally Qualified Health Centers – 330 Grantees).

In the instance of ADAPs, 318 Grantees, and 330 Grantees, 340B programmatic revenues are central to program design. Indeed, for many of these grantees, without 340B, these entities would not otherwise qualify for their grantee status due to a lower likelihood of sustainability. Each grantee is required to provide planning of sustainable programmatic revenues in order to qualify for the federal grant.

Let us describe how these dollars are reinvested and why imposing a UPL is a threat to health equity and public health programming in specificity.

ADAP: Maryland's AIDS Drug Assistance Program received about $24 million from the federal government in 2021 according to the most recent program monitoring report from the National Association of State and Territorial AIDS Directors (NASTAD). Maryland, however, did not provide detailed budgetary reporting to NASTAD. Instead, we must look at reporting from similarly situated states. Few states actually provide any state matching dollars to their ADAP and when they do, those dollars are often less than 10% of the federal award. However, rebate revenues generated from the program tend to exceed 16% (often times, quite a bit more) additional value in sustaining the program. In another state that received about the same amount as Maryland did in federal award, the ADAP also generated about $10 million in rebate revenues – a near 50% additional value. That value is reinvested in providing no-cost to patient antiretroviral medications to patients *or* used to pay for approved plan premiums to further overall access to care for recipients in Maryland living at or below 400% of the Federal Poverty Level but above Medicaid qualifying income levels. Revenues generated from 340B via the state's ADAP means the ADAP is sustainable, serves half again as many patients as it would otherwise, and helps move the state to achieving its health equity and public health goals.

Imposing an upper payment limit would reduce the value of those rebates, thus reducing how many patients the ADAP might be able to serve. Remember, ADAP serves severely patients who would not otherwise be able to afford or access their HIV medications.

STI Clinic Grantees and Subgrantees: 318 Grants are awarded to state and local health departments which then subcontract out to local clinics with expertise in delivering services. These grants are often relatively small compared to ADAPs, with awards often barely reaching some hundreds of thousands of dollars rather than millions. These subgrantees are some of the largest public providers of pre-exposure prophylaxis (PrEP) in the country. For some clarity as to exactly how well these programs work, while many subrecipients receive some financial support for their programming, some of the subgrantees only qualify for 340B because of in-kind agreements – which might just be HIV rapid test kits. In turn, these subgrantees are so efficient at delivering HIV screening and enrolling appropriately identified patients into PrEP services that their entire program model is based off realizing 340B savings.

A UPL would have even more of a dramatic effect on 318 subgrantees than it would on the ADAP.

Federally Qualified Health Centers: 330 grantees have a dedicated mission to serve impoverished communities "regardless of ability to pay". 330 grantees are required to offer healthcare services with sliding fee scales, limited to no collection practices, and are a key gateway for patients who need the most help. Some FQHCs utilize their 340B savings to offer food assistance, transportation, even housing in some situations. Others use their 340B savings to expand programming to include mental health and substance use services, particularly when state dollars are not readily available to support these non-profit healthcare providers. Each site is specifically selected due to the nature of the area necessarily being "underserved" – to be direct FQHCs serve communities that are more Black, more Brown, more Woman, and more Queer than their hospital counterparts. And they do so, at times, using those same rebates to provide patients with no-cost medication. Indeed, FQHCs are some of the best stewards of the program.

A UPL would necessarily reduce the rebate values realized by FQHCs and reduce those entities' ability to serve the most marginalized of Marylanders.

The Board Must First Establish Access Monitoring Prior to Beginning Any "Cost Review Study"
In order to appropriately appreciate the patient experience with regard to the issue of "affordability", the Board must first understand that "affordability" is but one arm of "access". An "affordable" medication means nothing if a patient cannot access that medication.

The Board has previously expressed concern regarding maintaining access – a comprehensive view of the patient experience. However, the Board has not established any definition of access nor has the Board meaningfully engaged in access monitoring deliberations. This must be done prior to proceeding with any additional steps, including "cost review study" or imposing rate setting. "Cost" cannot be sufficiently explored without distinguishing between particular cost burdens and the drivers of those burdens. For example, is "cost" comprehensive of transportation concerns in rural areas which may be prohibitive of any cost-sharing a patient might face at a pharmacy counter? Is "cost" comprehensive of an under reimbursement a pharmacy may face, resulting in not being able to fill a patient's needed prescription? Does "cost" include the necessary diagnostics or the even the provider visit required to get a prescription in the first place? How does the Board intend to differentiate throughout any "study"? What entities will the Board employ to ensure access is not harmed under a UPL? Is "cost" assessed to include those savings realized by diverted hospitalizations? Will "cost" consider the burden patients may face if additional utilization management is imposed to prefer a particular medication selected by the Board for UPL? Will the Board consider the accessibility of manufacturer patient assistance programs in determining "cost" to patients?

These questions deserve clear, precise answers prior to beginning any "cost review study".

Lessons From Colorado
As an organization lending our expertise and voice to people living with HIV across the nation, CANN was deeply involved in the "affordability review" process of Genvoya in Colorado. Genvoya is similarly situated to Biktarvy is some ways – to be clear, Genvoya may not be prescribed for PrEP and is no longer "first line treatment". Biktarvy, however, can be prescribed as PrEP and is considered "first line" for the treatment of HIV. Colorado's Board spent more than 50 hours across a few short months, in a deeply flawed process. Patient impact surveys suffered from design bias, asking leading questions, were not well distributed, and were open – initially – for a mere 21 days. To put this into context, Ryan White needs assessment surveys take the better part of a year to fully grasp program impact. In addition to this, Colorado engaged in "small group meetings" of patients, caregivers, providers, and manufacturers throughout the review data gathering process.

It was, in a word, **traumatic** for patients desperately concerned about losing access to their medications. Hours upon hours were spent explaining that sufficient systems exist to blunt out-of-pocket expenditures for patients through a variety of ways, including public programs like the AIDS Drug Assistance Program.

All of this to arrive to the decision that Genvoya was "not unaffordable" to patients in Colorado and, indeed, imposing a UPL would potentially harm public health programming dependent upon 340B savings generation.

Conclusions
CANN appreciates the very noble goal of reducing patient cost burdens. We recognize "affordability" is an essential arm of "access" and, ultimately, access to care for people living with HIV is our greatest priority. We share this goal with the Board. The unfortunate reality is that Board was not empowered by the legislature with an appropriate tool to address issues of access. Addressing discriminatory plan design, PBM abuses, under

reimbursement already harming non-chain, independent pharmacies, curbing utilization management practices that delay and deny care – all of these would better serve Marylanders than the process before you.

We wish to be one hundred percent clear: a "cost review study" is harmful to patients on an emotional level. People living with HIV are disproportionately Black and Queer. We already face discrimination elsewhere in our lives, struggles to access care, and harmful policies and practices which hurt our ability to trust institutions of power, including the healthcare system writ large. Including this very Board. Engaging in a process which will ultimately ask the question "Are you worth our dollars?" is not going to improve that situation.

Even the thought of imposing a UPL is a "threat" to our access to care through the ADAP, STI Clinics, and FQHCs because of mechanisms of funding outside of this Board's purview. Reducing the value of 340B by imposing a UPL necessarily divests from marginalized communities.

It is with a very sincere shared interest we ask this Board to halt the "cost review study" process, any determination of medications for review, particularly Biktarvy, and consider the content laid above.

- Establish access monitoring metrics
- Establish access monitoring processes
- Study the potential impacts to 340B served programs and entities
- Ensure "cost review study" content is appropriately designed and unbiased
- Ensure "cost review study" processes will not disadvantage, deprioritize, or otherwise harm patients

There is good work to be done by this Board but it won't be found with a "cost review study" as currently described or a UPL.

CANN looks forward to working with the Board and we are readily available to staff to discuss our concerns and find collaborative solutions.

Ever in your service,

Jen laws
President & CEO
Community Access National network

Submitted for Public Comment: Maryland PAB
Meeting: March 25, 2024
Agenda Item: Public Comment, Cost Review Study

March 20, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

I am an infectious disease physician and HIV care provider. I work at the Greater Baltimore Medical Center, a non-for-profit organization. I see patients on Medicaid and Maryland ADAP. Most of my patient are on Biktarvy and are doing well. The patient population I care for are mostly Brown, Black and queer. Many of them have other medical needs such as meatal health issues most of time the underlying condition that led to HIV infection in the first place. These patients have serious issues of trust and compliance. These complex population is challenging to care for.

As a long-term care provider I am very concerned that the cost review study of Biktarvy may impact accessibility to the drug by my patients who are doing well on it. As of now, all my patient have readily access to the drug. Having their medication for HIV taken care of as it is at present time, alleviates some of the many worries of this population. I request the board that before HIV medication specifically Biktarvy can be put to evaluation of cost, please make an assessment of the potential impact that cost

review will have in the accessibility to the drug in the state of Maryland

Thank you for the attention to this concern.

Respectfully,

Karoll Cortez, MD
Infectious Disease
Internal Medicine
Greater Baltimore Medical Center

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March 20th, 2024
Maryland Prescription Drug Affordability Board (PDAB)
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

I am writing to express my deep concerns regarding the inclusion of the HIV drug - BIKTARVY in the cost review process currently being undertaken by the Board. As a HIV specialist medical provider, concerned member of the community and an advocate for LGBTQIA+ health, particularly in the context of HIV prevention and treatment, I believe it is crucial to reconsider this decision due to several significant factors.

Firstly, BIKTARVY holds orphan drug status granted by the FDA, making it crucial in the pediatric treatment of HIV. This status is important for several reasons, including the limited market for pediatric HIV medications, the incentives it provides for research and development, the encouragement of pediatric-specific formulations, and ensuring continued access to essential medications for children living with HIV.

Secondly, imposing an arbitrary upper payment limit (UPL) on medications like BIKTARVY could have severe negative impacts on 340B entities, including ADAPs, STI Clinic Grantees, and Federally Qualified Health Centers. These entities rely on 340B programmatic revenues to sustain their programs, serve more patients, and achieve health equity and public health goals. A reduction in allowable reimbursement rates would directly reduce the value of rebates and limit the ability of these entities to serve marginalized communities.

Thirdly, it is paramount to consider the broader societal and structural determinants of health (SSDOH) when evaluating HIV medications. The Maryland PDAB must thoroughly assess these factors, including access issues, discriminatory plan designs, and the impact on public health efforts to combat HIV, before proceeding with any cost review study.

Furthermore, I urge the Board to take into account the lessons learned from similar processes in other states, such as the "affordability review" of Genvoya in Colorado. Rushing through such evaluations without a comprehensive understanding of the implications can lead to traumatic experiences for patients and harm public health programming dependent on 340B savings generation.

In conclusion, I appreciate the noble goal of reducing patient cost burdens, but it is essential to do so in a manner that does not compromise access to essential medications, particularly for populations that are made vulnerable - like those affected by HIV. More importantly, we must collaborate and support key **Ending the HIV Epidemic (EHE) strategic goals** in Maryland,

which highlights access as one of the major barriers to ending this epidemic. Therefore, I respectfully request that the Maryland PDAB reconsiders including BIKTARVY in its cost review process and takes a more comprehensive and thoughtful approach to evaluating HIV medications and crucial services associated with it.

Thank you for considering my concerns and taking action to ensure access to vital treatments for all individuals in need.

Sincerely,

Mickey Dhir (He/Him/His), MS, MBA, AGPCNP-C, AAHIVS, PHD(c)
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INFECTIOUS DISEASES CONSULTANTS, LLC

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March 19, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Board,

This letter is being written to you in reference to the upcoming meeting of the Maryland Prescription Drug Affordability Board, and more specifically about the inclusion of an HIV medication, Biktarvy, in this review.

I am an Infectious Diseases specialist who has practiced in Maryland for over 30 years taking care of patients with a diverse array of Infectious issues. I have been involved in diagnosing and treating patients with HIV/AIDS since my early years of training as a resident. A portion of my practice involves taking care of HIV patients, both as inpatients as well as a large panel of outpatients. It is amazing to see the strides we have made over the last few decades in treating this disease taking it from an illness with a certain death sentence to one that is a chronic, controllable disease. The medications of today are truly amazing and one of the stalwarts of my practice is Biktarvy. A large percentage of my HIV patients are doing extremely well on this medication and living normal lives. It is recommended as a first line HIV medication in national guidelines and with good reason. It helps controls the HIV disease over the long term and allows patients to lead a healthy life.

The board seeks to review whether this stalwart medication should have a price ceiling in the future. In my opinion, any attempt to do so would adversely affect the availability and affordability of this medication. Many patients already have a co-pay and forcing them to pay additional cost would be prohibitive for some. Capping cost could also affect re-imbursement for pharmacies and organizations such as MADAP which could diminish their ability to provide medications to these HIV patients.

Providing excellent care to all patients is why I became a physician and restricting the use of an excellent mainstream medication such as Biktarvy for HIV runs counter to that ethos. I implore you to remove this medication from your discussion so that I and my fellow HIV providers can continue to provide the best care for our HIV patients.

Please do not hesitate to contact me if you have any further questions.

Sincerely,

Paul A. Eder, M.D.

March 20, 2024

Via email (*comments.pdab@maryland.gov*)

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: March 25 Prescription Drug Affordability Board Meeting

Dear Members of the Prescription Drug Affordability Board:

I am writing on behalf of Gilead Sciences, Inc. ("Gilead"), in response to the Prescription Drug Affordability Board's ("PDAB") recent identification of Biktarvy® for a potential cost review. This is Gilead's first letter to the PDAB, and we plan to submit additional comments if Biktarvy remains on the list of drugs under consideration. Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for people with life-threatening diseases in areas of unmet medical need, and has been a leading innovator in HIV for more than 30 years. Biktarvy is a single-tablet regimen that provides unique value for patients with HIV and is recommended as an initial treatment regimen for most people with HIV by the U.S. Department of Health and Human Services' HIV treatment guidelines.[1]

PDABs and Upper Payment Limit ("UPLs") operate on the false assumption that they improve affordability and access to a drug in a state, despite evidence that government price setting reduces patient access. The PDAB has not finalized its UPL plan and should not move forward with selecting drugs for a cost review until that plan is established. In particular, the PDAB should not select Biktarvy for a cost review because it is the first step toward a potential UPL. A UPL is likely to disrupt treatment for HIV, leading to adverse clinical outcomes and increased transmission rates for vulnerable populations that are already experiencing disparities and inequities in care. This would undermine important progress that Maryland has made in controlling its HIV epidemic, in part because Biktarvy is affordable and accessible to HIV patients in Maryland. HIV requires special consideration because it is both infectious and currently not curable, therefore it is critical to avoid treatment delays or disruptions, which would increase the risk of transmission. **For these reasons, we urge the PDAB to remove Biktarvy from its list of drugs being considered for a cost review.**

[1] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/intro-and-overview?view=full

In our detailed comments below, we explain that Biktarvy should not be selected for a cost review for the following reasons:

I. **A UPL on Biktarvy would likely result in unintended consequences, including treatment delays and interruptions.**
II. **Treatment delays and interruptions allow HIV to replicate in the body, worsen clinical outcomes, and increase the risk of resistance and HIV transmission, leading to higher health care resource utilization and undermining the state's efforts to end the HIV epidemic.**
III. **Delays and disruptions in HIV treatment disproportionately affect vulnerable populations and exacerbate disparities experienced by minority groups, conflicting with the Moore Administration's goal of ensuring health care equity in Maryland.**

Additionally, we urge the PDAB to adhere to fair, reasoned, and transparent processes that allow for meaningful engagement by manufacturers and other stakeholders as it selects drugs and conducts cost reviews.

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I. A UPL on Biktarvy would likely result in unintended consequences, including treatment delays or interruptions.

HIV is a potentially deadly and uncurable infectious disease and not an appropriate condition for untested price setting policies. Selecting Biktarvy for a cost review would begin a process toward potential government price setting in the form of a UPL. The PDAB has not finalized its UPL implementation plan or fully considered how different implementation paths could trigger unintended consequences for people currently taking the affected medicines. However, experience from government price setting policies implemented in other countries in the Organization for Economic Co-operation and Development (OECD) provides evidence that policies like UPLs do, in fact, reduce patients' ability to access new medicines. On average, patients in other OECD countries that rely on various forms of pharmaceutical price-setting, have access to only 29% of new medicines, while patients in the United States have access to 85%.[2] We are not alone in raising these concerns. Community Health Centers and pharmacies have also highlighted concerns that a UPL could disrupt patient access.[3] Given the profoundly negative impact that state actions reducing access to Biktarvy could have on people with HIV, we urge Maryland not to select it for a cost review.

[2] Richard Kane. PhRMA. New global analysis shows patient access challenges around the world. April 12, 2023. https://phrma.org/en/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world.
[3] *See,* NACDS letter to the Maryland Prescription Drug Affordability Board. Re: Upper Payment Limit Action Plan. November 13, 2023. *See also,* Mid-Atlantic Association of Community Health Centers letter to The Honorable Pamela Beidle. Re: Senate Bill 388. February 7, 2024.

Disruption of patient access through a UPL would be particularly concerning for Biktarvy because it is currently used to treat tens of thousands of people living with HIV in Maryland, thereby supporting the state's efforts to end the HIV epidemic, and reflecting the current strong access and affordability patients have to Biktarvy. The PDAB should ensure patients can continue to access Biktarvy because of its many favorable attributes, including long term efficacy, rapid reduction in viral load to undetectable levels, high and durable resistance barrier, use for rapid start and restart, and higher adherence and persistence.[4] For these reasons, it would be imprudent for the PDAB to risk disrupting HIV treatment by selecting Biktarvy, or any medicine to treat HIV, for a cost review.

II. Treatment delays and interruptions allow HIV to replicate in the body, worsen clinical outcomes, and increase the risk of resistance and transmission, leading to higher health care resource utilization and undermining the state's efforts to end the HIV epidemic.

Any public policy that introduces new barriers to access to HIV treatments or interrupts care for patients currently virally suppressed on therapy will result in new HIV infections. Patient and provider choice of therapy for HIV is critical because adherence to effective treatment of HIV can reduce the amount of HIV in the body to an undetectable level, which not only improves that patient's individual health and well-being but also has the added public health benefit of preventing sexual transmission of the virus. Researchers at the National Institutes of Health found that maintaining an undetectable viral load for at least six months results in people with HIV having no risk of sexually transmitting HIV to partners.[5] In contrast, delays in initiating HIV treatment, gaps that might occur as a patient switches from one regimen to another, or relegating a person living with HIV to a suboptimal or less tolerated treatment regimen will negatively impact their ability to adhere to treatment and remain virally suppressed.[6]

Reductions in viral suppression would not only result in worse health outcomes, treatment failure and higher healthcare costs, but also an increased risk of HIV transmission for people that are not

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[4] See, e.g., Gilead Sciences, Inc. Biktarvy® Patient Brochure [Internet]. 2021 Feb. Available from: Link; Orkin C, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. Lancet HIV. 2020 Jun;7(6):e389-e400. Available from: Link; Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Panel on Antiretroviral Guidelines for Adults and Adolescents; 2023 Dec 6. Available from: Link; Altice F, et al. Adherence to HIV treatment regimens: systematic literature review and meta-analysis. Patient Prefer Adherence. 2019 Apr 3;13:475-490. doi: 10.2147/PPA.S192735. PMID: 31040651; PMCID: PMC6452814. Available from: Link

[5] Eisinger RW, Dieffenbach CW, Fauci AS. HIV Viral Load and Transmissibility of HIV Infection: Undetectable Equals Untransmittable. *JAMA*. 2019 Feb 5;321(5):451-452.

[6] Yuan Y, et al. "Determinants of discontinuation of initial highly active antiretroviral therapy regimens in a US HIV-infected patient cohort." HIV Med. 2006 Apr;7(3):156-62. doi: 10.1111/j.1468-1293.2006.00355.x.

virally suppressed to other Marylanders.[7,8] All of these results would drive up healthcare costs for Maryland. Avoiding just one new HIV infection can reduce lifetime healthcare costs – which for many patients may be borne partly or entirely by Medicaid – by $850,557 on average; annual and cumulative healthcare costs were up to seven times higher for people living with HIV compared to those without HIV.[9]

Maryland's annual rates of HIV diagnoses and incidence are now decreasing, according to preliminary 2023 data, compared to 2021.[10] This indicates progress in the state's fight against HIV/AIDS, with major improvements seen across the state and in key communities, including in Baltimore. These gains follow sustained, dedicated resourcing and collective efforts following declared "state of emergency" measures in recent decades, including efforts to identify people living with HIV and connect them to care.[11] However, disrupting care for patients who are stable on or starting a HIV treatment, such as Biktarvy, will negatively impact many of the more than 31,000 people living with HIV in Maryland.[12] According to Maryland's most recently published Epidemiology Profile, less than 60% of individuals diagnosed with HIV in Maryland had achieved viral suppression in 2022.[13] And the rate of people living with HIV remains higher in Maryland than the US overall.[14] This shows that there remains a significant need to improve diagnosis and treatment of HIV in the state, rather than introduce new price setting policies that are likely to disrupt patient care.

Drug resistance is another serious consequence that can occur when HIV treatment is disrupted. Resistance can lead to treatment failure and may eliminate any further treatment from the class of drugs that the resistance impacts. Treatment failure requires patients to switch to alternative treatment regimens that may be more limited and costlier, both in poor outcomes for the patient and increased health resource utilization. Partial adherence to treatment regimens, where a patient takes some of their HIV medications but not all, can occur when people living with HIV are switched off a treatment regimen that is working to one that might be more difficult to adhere to (e.g., requiring different dosing) for that patient. Partial adherence poses a significant public

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[7] Von Wyl V, Klimkait T, Yerly S, et al. Adherence as a predictor of the development of class-specific resistance mutations: the Swiss HIV Cohort Study. *PLoS One*. 2013;8(10):e77691. Published 2013 Oct 16. doi:10.1371/journal.pone.0077691

[8] Bangsberg DR, Acosta EP, Gupta R, et al. Adherence-resistance relationships for protease and non-nucleoside reverse transcriptase inhibitors explained by virological fitness. *AIDS*. 2006;20(2):223-231. doi:10.1097/01.aids.0000199825.34241.49

[9] Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *Pharmacoecon Open*. 2020;4(4):687-696.

[10] HIV Epidemiological Update, presented by Colin Flynn, ScM; Chief, Center for HIV Surveillance, Epidemiology and Evaluation. March 7, 2024.

[11] https://www.advocate.com/health/health-news/2002/12/05/baltimore-mayor-declares-aids-quotstate-emergencyquot-7125

[12] https://health.maryland.gov/phpa/OIDEOR/CHSE/pages/statistics.aspx

[13] https://health.maryland.gov/phpa/OIDEOR/CHSE/SiteAssets/Pages/statistics/Maryland-Annual-HIV-Epidemiological-Profile-2022.pdf

[14] https://aidsvu.org/local-data/united-states/south/maryland/

health threat and can lead directly to the development of resistant forms of the virus.[15] In addition, the drug-resistant form of the virus can then be spread to and infect other patients, which further undermines efforts to end the HIV epidemic.[16] Biktarvy has a high and durable barrier to resistance,[17] minimizing the risk that partial adherence to the medicine will lead to development of resistant forms of HIV. Unfortunately, resistance is more likely with other treatments that patients are likely to take if they lose access to Biktarvy because of a UPL.

Unlike other treatments for HIV, Biktarvy can support "rapid start," a process in which patients can start treatment immediately upon diagnosis of HIV, even before results from baseline lab testing are available.[18] Delays in initiating therapy lead people to stop engaging in care and lengthen the time for them to reach viral suppression, whereas immediate treatment upon diagnosis is associated with improved virologic suppression even five years later.[19] Research has also found that earlier initiation compared with later initiation reduced HIV transmission, progression to AIDS, and the incidence of serious medical conditions including cardiovascular or vascular disease, liver disease, end-stage renal disease, new-onset diabetes mellitus, and non-AIDS malignant disease.[20] Because of the clinical benefits of Rapid Start, providers need immediate access to the treatment regimen that is most appropriate for the patient and rapid initiation.

III. Delays and disruptions in HIV treatment disproportionately affect vulnerable populations and exacerbate disparities experienced by minority groups, conflicting with the Moore Administration's goal of ensuring health care equity in Maryland.

The PDAB should recognize that pursuing price-setting policies specifically for HIV treatments like Biktarvy risks disproportionately impacting care for disadvantaged people living with HIV, as those individuals are most likely to suffer from disruptions in care. HIV disproportionately impacts socially marginalized and disenfranchised populations, particularly sexual minorities,

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[15] Von Wyl V, Klimkait T, Yerly S, Nicca D, Furrer H, et al., Adherence as a Predictor of the Development of Class-Specific Resistance Mutations: the Swiss HIV Cohort Study, 8 *PLoS ONE* e77691 (2013).
[16] Guyer B, et al., AMCP NEXUS, Abstract #17 (2010).
[17] See, e.g., Sax PE, et al; GS-US-380-1489 and GS-US-380-1490 study investigators. Bictegravir/emtricitabine/tenofovir alafenamide as initial treatment for HIV-1: five-year follow-up from two randomized trials. EClinicalMedicine. 2023 May 11;59:101991. https://pubmed.ncbi.nlm.nih.gov/37200995/
[18] *See* Lodi S., Phillips A., Logan R., et al., Comparative effectiveness of immediate antiretroviral therapy versus CD4- based initiation in HIV-positive individuals in high-income countries: observational cohort study, 2 LANCET HIV E335-43 (2015).; Highleyman, Liz. RAPID Program Leads to Faster HIV Suppression. AIDSmap website. https://www.aidsmap.com/news/jul-2015/same-day-startantiretroviral-treatment-leads-faster-hiv-suppression-san-francisco. Published July 23, 2015.
[19] *See id*.
[20] *Id* Cohen, M. S., Chen, Y. Q., McCauley, M., et al., (2011). Prevention of HIV-1 infection with early antiretroviral therapy. The New England journal of medicine, 365(6), 493–505. doi.org/10.1056/NEJMoa1105243.

and communities of color.[21] Therefore, state actions disrupting care for HIV would disproportionately harm some of the most vulnerable groups in Maryland who face many barriers that can limit their ability to access and adhere to treatment. As an example, Black people represent 30.2% of Maryland's population but accounted for 71.3% of all people living with HIV in the state and 70.6% of new HIV diagnoses in 2021.[22] Also reflecting these disparities, Prince George's County accounted for the highest number (258, 34.4%) of HIV diagnoses, while the rate was highest in Baltimore City (32.6 per 100,000 population).[23] These are the two counties with the highest percentage of Black residents.[24] In addition, people living with HIV disproportionately experience the negative impacts of social determinants of health, such as stigma, poverty, and homelessness, that lead to higher barriers in accessing HIV care and attaining favorable treatment outcomes.[25] Disrupting HIV care would undermine Governor Moore's commitment to "foster a healthcare system that improves health and wellbeing, and where all Marylanders have access to affordable health care services."[26]

In part because of these disparities in social determinants of health and the nature of HIV, it is even more important to ensure that patients can work with their provider to select the treatment that is most appropriate for them. Individualized treatment allows for maximization of clinical benefits: increasing the likelihood of adherence, which can improve the opportunity for viral suppression, leading to better control of HIV, significantly decreased rates of hospitalization and lower healthcare costs,[27] reduced risk of treatment discontinuation, and avoidance of adverse consequences such as drug resistance and transmission of HIV.[28] The US Department of Health and Human Services guidelines on HIV recognize the importance of patient and provider choice, stating "Regimens should be tailored for the individual patient to enhance adherence and support long-term treatment success. Considerations when selecting an [antiretroviral] regimen for an individual patient include potential side effects, patient comorbidities, possible interactions with

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[21] Pellowski J., Kalichman S., Matthews K., et. al., (2013). A pandemic of the poor: social disadvantage and the U.S. HIV epidemic. *The American psychologist*, *68*(4), 197–209. doi.org/10.1037/a0032694

[22] AIDSVu.org. Local Data: United States. Accessed from https://aidsvu.org/local-data/united-states/.

[23] Ibid.

[24] https://www.indexmundi.com/facts/united-states/quick-facts/maryland/black-population-percentage#table.

[25] CDC. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States 2020 Cycle (June 2020–May 2021). https://www.cdc.gov/hiv/library/reports/hiv-surveillance-special-reports/no-29/index.html.

[26] Moore Miller for Maryland. A Healthy Maryland Today. Available at: https://wesmoore.com/wp-content/uploads/2022/05/Wes-Moore-For-Maryland-Health-Care-One-Pager.pdf.

[27] Sutton S, et al., Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy, 36 *Pharmacotherapy* 385-401 (2016); Sutton S, et al., Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks, 22 American Journal of Managed Care 242-48 (2016).

[28] Yager J, et al., Relationship Between Single Tablet Antiretroviral Regimen and Adherence to Antiretroviral and Non-Antiretroviral Medications Among Veterans' Affairs Patients with Human Immunodeficiency Virus, 31 *AIDS Patient Care and STDs* 370-76 (2017); Cohen C, et al.; Association of Partial Adherence (PA) To Antiretroviral Therapy With Hospitalizations and Healthcare Costs in an HIV Population, 15 Journal of the International AIDS Society 18060 (2012); Bangsberg DR, et al., Adherence-Resistance Relationships For Protease And Non-Nucleoside Reverse Transcriptase Inhibitors Explained By Virological Fitness, 20 *AIDS* 223-32 (2006).

concomitant medications, results of pretreatment genotypic drug-resistance testing, and regimen convenience."[29] For these reasons, it is critical to reduce or eliminate all manner of barriers to receiving effective treatment and care for HIV, not add to their challenges by introducing unnecessary price-setting mechanisms.

IV. The process of selecting drugs and conducting cost reviews should be fair, reasoned, and transparent while allowing for meaningful engagement from Gilead and other stakeholders.

As the PDAB approaches its first discussion of drugs that may be referred to the Stakeholder Council and subsequently undergo cost review, the PDAB should follow processes that are fair, reasoned, and transparent.

The PDAB must ensure that its decisions are supported by substantial evidence and are not arbitrary and capricious.[30] The PDAB identified eight drugs for discussion at the upcoming PDAB meeting but provided no explanation for its identification of certain drugs and not others. The PDAB has not released a list of drugs eligible for cost review or explained the methodology or data used to identify eight drugs from that list or why it did not include 20-25 drugs on the list as the PDAB Executive Director had previously stated would occur. In addition, the PDAB has not provided clarity about what will happen if a drug is deemed unaffordable. Specifically, the PDAB has not finalized its UPL Action Plan or provided any detailed timeline information in writing. This vacuum of information creates uncertainty for the patients who rely on Biktarvy. The PDAB should select drugs for cost review only after full consideration of all relevant data and information and a thorough explanation of its decision to the public.

The PDAB must provide manufacturers with a meaningful opportunity to weigh in before the PDAB makes decisions. Manufacturers can offer a unique and valuable perspective to the PDAB. They can correct or clarify outdated or incomplete data, explain technical details, and contextualize information about the drug at issue. In selecting eight drugs for discussion at the upcoming PDAB meeting, however, the PDAB failed to provide manufacturers (and other stakeholders) with an opportunity to serve this critical role. Instead, the PDAB selected drugs for discussion in private, based on a vague and unpredictable methodology, and in reliance on data that it has not made available to the public. In addition to potential concerns regarding Maryland's Open Meetings Act,[31] this approach deprives manufacturers of a meaningful opportunity to comment on the inclusion of their drugs on the initial drug list. The PDAB should

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[29] HHS, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, Treatment Goals (Jan. 28, 2016), https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/treatment-goals?view=full.

[30] *See, e.g.*, Md. Code Ann., State Gov't § 10-222(h)(3); *Maryland Bd. of Pub. Works v. K. Hovnanian's Four Seasons at Kent Island, LLC*, 425 Md. 482, 514 n.15, 42 A.3d 40 (2012).

[31] *See* Md. Code Ann., Gen. Provis. § 3-301.

address this issue and ensure that Gilead has an opportunity to meaningfully participate in the selection and (if necessary) the cost review process going forward.

The PDAB should also provide appropriate procedures for engagement with patients and other stakeholders to make reasoned cost determinations, including reasonable efforts to protect privacy. To date, the PDAB has not established any process for patients or other stakeholders to share their experiences other than through general public comment. This process is inadequate for drugs like Biktarvy, considering public stigma often associated with HIV and the socioeconomic barriers that confront many people living with HIV. In addition, the PDAB has not made replays of their meetings available to the public, despite multiple requests by members of the Stakeholder Council and concerns raised by the General Assembly. Other State PDABs do provide this tool. Given these potential barriers, the PDAB's current process does not allow for meaningful patient and other stakeholder engagement in the process.

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In conclusion, Biktarvy plays a crucial role in Maryland's goals to end the HIV epidemic and supports Governor Moore's priority of ensuring all Marylanders have access to affordable healthcare services. To avoid disrupting the many patients using Biktarvy to suppress their HIV virus, it is important that the PDAB not select it for a cost review. If you have any questions or wish to notify Gilead about future PDAB actions, please do not hesitate to contact me at kristie.banks@gilead.com.

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

HIV+HEP
POLICY INSTITUTE

March 20, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive
Suite 112-114, Bowie MD, 20715

Re: Testimony on the Selection of Drugs for Referral to Stakeholder Council

Dear Board Members:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Given the important nature of prescription drugs to the life-saving treatment of HIV and hepatitis B, and now, the cure of hepatitis C and the prevention of HIV, we have long advocated for affordable access to prescription medications. We appreciate the opportunity to comment and support and share the committee's intent to lower out-of-pocket costs for consumers. **We specifically offer comments on the selection of HIV/AIDS medications.**

The amount consumers pay for their prescription drugs is mainly driven by their insurer and pharmacy benefit manager (PBM). In addition to monthly premiums, consumers then can pay an annual out-of-pocket cost of up to $9,450 if they are an individual or $18,900 if they are a family for most private insurance plans[1]. The amount that is paid for prescription drugs is determined by the insurer and the PBM, that places the drug on various "tiers" that are associated with differing cost-sharing levels. Sometimes, these costs are associated with nominal copays, such as $10, $25, or $35 dollars, while others can be as high as $250 per month and expressed in terms of co-insurance, or a percentage of the list price of the drug (up to as much as 50 percent). While co-insurance is used in determining patient cost-sharing for prescription drugs, it is rarely used for any other medical service, and no other health care expenditure forces patients to pay based on the list price of an item.

Plans also have various levels of deductibles before their insurance kicks in. According to CMS, the 2024 silver plan median deductible in 2024 is $5,726 and for bronze plans, $7,239.[2]

According to CMS' 2022 National Health Expenditures report, while overall health care spending grew at 4.1 percent in 2022, out-of-pocket spending increased substantially higher at 6.6 percent in 2022 to

[1] https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/
[2] "Plan Year 2024 Qualified Health Plan Choice and Premiums in HealthCare.gov Marketplaces," CMS, last modified 10/25/23, https://www.cms.gov/files/document/2024-qhp-premiums-choice-report.pdf.

$471.4 billion. For prescription drugs, out-of-pocket spending totaled $56.7 billion, or 14 percent of the total spending on prescription drugs. This represents an increase of 11.6 percent in 2022 after slower growth of 6.4 percent in 2021. However, for hospital care, which accounts for more than three times more of the total spending than prescription drugs, patients were responsible for paying only 2.6 percent. Despite the much smaller total amount of spending for prescription drugs, the out-of-pocket spending for prescription drugs ($56.7 billion) was higher than all the out-of-pocket spending for hospitals ($35.1 billion).[3] This is due to insurance benefit design and it is no wonder that the American people are complaining so much about the costs of their drugs, because they are being forced to pay more in out-of-pocket costs by their insurers.

And we know when out-of-pocket cost are too high, patients don't pick up their drugs, which impacts their health and well-being. According to an IQVIA analysis, due in part to high costs, an estimated 92 million prescriptions were abandoned at the pharmacy in 2022 (this compares to 81 million in 2021), with the abandonment rate over one in three for prescriptions above $75 in out-of-pocket costs. Additionally, for prescriptions with a final cost above $250, 53 percent are not picked up by patients, as compared with 7 percent of patients who do not fill when the cost is less than $10.[4]

This is why **we believe policymakers should focus on those issues that directly impact patients, such as PBM regulation and reform, standard plan designs with reasonable deductibles and nominal copays, and ensuring copay assistance counts.** We note that the General Assembly is currently considering HB 879, legislation that would ensure that copay assistance programs will count toward deductibles and out-of-pocket maximums, and the Senate is considering SB 595.

Setting a price of an individual drug would be a very complex endeavor to undertake and not a function of state government. While the federal government is attempting this for some drugs in the Medicare program, it is under litigation and proving to be extremely difficult to execute. While we admit that drug pricing is highly opaque, we do know that it is based on multiple complicated factors. Pharmaceutical manufacturers are involved in hundreds of research and development projects at one time in the search for a successful launch of a new drug. Years and years of research and clinical trials go into the development for that one new drug, while at the same time hundreds of molecules and their combinations are studied that do not result in a viable product. This is a long and costly process and the development of that one successful drug can cost $2 billion. Maryland is home to many biotech and other life science enterprises and should not adopt policies that, however well-intended, adversely impact new drug development.

Most new drug research results in failures, which are very costly. While there is much attention to the high list price of these successful drugs, the cost of all the failures, and all the other functions of a pharmaceutical company, must be embedded in the that price. So, while a company can make a high level of profit off one drug focusing on one health condition, they can also spend billions of dollars on failures in that same focus area, along with all the other areas of research on other health conditions

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[3] "National Health Expenditure Data," CMS, last modified 12/13/23, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet#:~:text=NHE%20grew%204.1%25%20to%20%244.5,18%20percent%20of%20total%20NHE.

[4] "The Use of Medicines in the U.S. 2022," IQVIA Institute, April 2022, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf, page 47.

that do not turn into successful products. Additionally, they are using the profits of today to invest in the successes and failures of tomorrow. Companies in the HIV space are working on longer acting treatment and prevention drugs, vaccines, and even a cure. Many companies are working on a cure for hepatitis B while so many others are working on better cancer treatments, and medications to treat other countless conditions such as Alzheimer's, diabetes, heart ailments, mental illness, arthritis, Lupus, epilepsy, rare diseases, and even aging.

People often call out the manufacturing cost of producing a specific drug. They may say a drug costs as little as a couple of cents to produce. While that is not true for all drugs such as biologics, it does not count the investment and resources needed to research and develop the drug, and construct and run the manufacturing sites.

Additionally, drug manufacturers do not collect the full list price of their drugs, with net prices falling for the last six years.[5] Other players in the drug supply chain receive a large and increasing share of the money. PBMs collect high rebates and there are other mandatory rebates in the Medicaid and 340B programs. These rebates are especially high in the HIV and hepatitis arena, and then there are additional rebates pharmaceutical manufacturers provide to states through the AIDS Drug Assistance Program.

Many existing programs for individuals with HIV and those taking preventive medications are part of a complex web involving federal, state, local, and industry programs that are currently making drugs accessible which may be made inaccessible by a state setting drug prices. The Board's decision on one medicine could change the pricing landscape in ways that undermine the clinical judgement and patient choice in favor of costs unrelated to care.

Companies provide free drugs to people who are uninsured and underinsured, and copay assistance to help people with insurance afford their medications. In fact, according to IQVIA, in 2022 manufacturer copay assistance brought down patient costs by nearly $19 billion and accounted for 23 percent of their out-of-pocket costs.[6]

Drug companies also operate in a global environment, as exemplified in the HIV and hepatitis arenas, and provide medications to millions of people in underdeveloped and underserved nations. The companies provide drugs to the PEPFAR program at very low costs and have voluntary licensing arrangements in place for generic medications.

On top of it, they must recoup and make all their money on a successful drug in a very limited amount of time before the drug goes generic and other companies can take advantage of the R&D and FDA approval and begin to produce it without any renumeration to the original patent holder. And unlike the PBM industry, the pharmaceutical industry is a very competitive market with hundreds of companies both in the United States and around the world developing new medications.

As you consider which drugs to select for further review, we ask you to consider the many complexities and factors that go into setting a price of a drug and the specific factors directly impacting HIV/AIDS medications.

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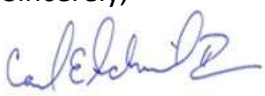
[5] https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html

[6] "The Use of Medicines in the U.S. 2022," page 41.

Thank you for the opportunity to comment on this process. If you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,



Carl E. Schmid II
Executive Director

Imran Chowdhury, M.D. | Kody Modjtabai, M.D. | Ali Amjadi, M.D.

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March 19, 2024

To whom It May Concern,

As the Prescription Drug Affordability Board considers the use of Biktarvy for Maryland patients, I would like to provide an opinion from an Infectious Disease practitioners perspective.

Given we are considering an HIV medication, I think it is important to remember that HIV is not similar to any other disease processes. HIV is a communicable disease unlike diabetes or high blood pressure. Furthermore, having HIV comes with certain stigmas social and other. This stigma often is a barrier to the treatment of our patient population.

This, however, is not the only barrier. There are other barriers which include the lack of understanding of the disease, the distrust of the healthcare industry, not to mention anxiety that is present just for having HIV.

Biktarvy currently is used in over 50% of patients with HIV. We lean on this medication heavily because it is sturdy, it is reliable, it can be used in patients with all renal functions, it can be used in most age ranges as well as in pregnancy. It is well tolerated and can be taken at any time with any food. In other words, it is the gold standard in HIV care. These qualities cannot be replicated by other alternatives.

It is because of all the above characteristics we have been able to reliably treat patients who were skeptical that a once daily and well tolerated pill would be effective.

At a time that we are still fighting an HIV epidemic in Maryland, where three of our counties are included in the top 50 counties in the country driving this epidemic, it is very important that we make all medication decisions with care.

Imran Chowdhury, M.D. | Kody Modjtabai, M.D. | Ali Amjadi, M.D.

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While I completely agree that cost is very important in allocating healthcare, I think is also very important to provide context to that cost.

By decreasing a patient's access to Biktarvy we are removing a valuable therapeutic option, we are introducing variability and possibly instability as we rotate through other medications to find another effective option. This is more pronounced in an at-risk population that will be effected disproportionately by your decision.

These hidden costs will eventually add up to more uncontrolled HIV cases and possibly transmission to other patients and therefore more health care costs.

For all the above reasons, I urged the Prescription Drug Affordability Board to forgo any limit to Biktarvy for use in our Maryland patients.

Sincerely yours,

Kody Modjtabai, MD
Infectious Disease

March 25, 2025

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

We appreciate the opportunity to provide public comment on the Board's preliminary list of prescription drug products being considered for review (Attachment A of the March 25th meeting agenda). With Maryland at the forefront of this cost review process, we look forward to how your work can utilize lessons learned from Colorado's Prescription Drug Affordability Board, and how our Board will continue pave the way for states around the nation. We appreciate your thoughtful consideration thus far.

Vincent DeMarco
President, Maryland Citizens' Health Initiative

Comments on Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council

Proposed Prescription Drug Products

We thank the Board, Stakeholder Council, and Staff for the work done to determine the prescription drug selection and cost review processes and are excited to see the first products being considered. Given the selection, we are pleased that health equity concerns appear to have been central in the determination process, and we encourage ongoing attention to this issue in any cost review discussions, as well.

We have the following thoughts regarding the below products:

1. *Drugs Undergoing Medicare Maximum Fair Price Negotiation (Farxiga & Jardiance):* given the inclusion of Farxiga and Jardiance in the list of Medicare Part D drugs selected for 2026 negotiations, we feel it would be best to adopt the Medicare Maximum Fair Price determined for these drugs and allow the Board to focus on products that are not under federal review.

2. *Type-II Diabetes/Heart Failure Medications:* given this crowded therapeutic category, it might be appropriate for the Board to consider setting a class-wide upper payment limit, should a cost review result in the determination to set one as to avoid singling out a single manufacturer.

3. *Drugs With Orphan-Drug Status (Biktarvy & Dupixent):* a study published in 2021 in Health Affairs shows that in 2018 more than 70% of the money spent on top-selling partial orphan drugs went to the

treatment of common diseases, meaning that these extended patent lives are driving up costs for patients using otherwise commonly prescribed medications. We would encourage the Board to determine what percentage of Biktarvy and Dupixent is prescribed for orphan designation treatment uses to see if the partial orphan drug status is contributing to affordability challenges for others.

COMAR 14.01.04.03I(2)
Oral and Written Comments Concerning Board Selection of Prescription Drug Product for Cost Review

We encourage the Board to prioritize collecting patient-centric input throughout this process, including by hosting a separate public hearing that is *specifically* designed to help the Board engage with patients, providers, and advocacy groups regarding the chosen prescription drug product. We would also encourage the Board to seek input from the community regarding:

1. Estimates of patient non-adherence for the prescription drug product. Polling indicates that nearly a quarter of Marylanders have rationed, skipped, or left a prescription unfilled due to cost. If a considering prescription drug product has high rates of non-adherence due to cost, this should be heavily weighted in the selection and cost review process.

2. The amount of patient assistance provided by manufacturers of the selected prescription drug product. Considerable patient assistance is essentially manufacturer acknowledgement that their product poses an affordability challenge. In addition to seeking additional data sources, community experience with patient assistance programs could provide helpful insight.

3. The cost to local governments. We encourage the Board to seek direct input from local leaders to determine if any of the selected prescription drugs are of considerable concern for them.

Other Considerations

The Board's work offers a unique opportunity to view a complete landscape of the affordability challenges high-cost prescription drugs cause the Maryland health care system and patients. Consideration of the impact high prescription drug costs place on our insurance premiums and taxpayer dollars are very important.

We applaud the inclusion of direct patient/consumer feedback in the Board's processes. We encourage that the input collection form that is currently in development invite comment that offers perspective into the real-life consequences of unaffordable prescription drugs. Including: *what hard decisions have Marylanders had to make in order to afford their medicines? How many people have rationed or skipped treatment due to cost, and how has that impacted their life? Have Marylanders had to sacrifice their savings or stability in order to get the prescription drugs they need?*

Should the Board & Staff wish to speak with Maryland patients as these forms are created, we would be happy to connect you with consumers willing to provide feedback. Additional patient perspectives can be found in the 2020 and 2022 reports that summarize the Prescription Drug Affordability Forums our coalition hosted around the state.

Maryland Commission
on LGBTQIA+ Affairs

STATEMENT OF JEREMY BROWNING
DIRECTOR, MARYLAND COMMISSION ON LGBTQIA+ AFFAIRS

Statement Submitted for Public Comment: Maryland PDAB
Meeting: March 25, 2024

March 20, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

My name is Jeremy Browning(he/him), and I am the Director of the Maryland Commission on LGBTQIA+ Affairs. The Commission was created by the 2021 Maryland General Assembly, and later altered in 2023, to assess challenges facing our LGBTQIA+ communities, establish best practices and recommendations for LGBTQIA+ inclusion, and provide testimony to legislative and administrative bodies. Learn more about the Commission here: https://goci.maryland.gov/lgbtq/

The Commission noticed that Biktarvy is included on Attachment A of the March 25, 2024 MD PDAB meeting materials for Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council. Last November, the Commission unanimously adopted their 2024 Policy Priorities, Recommendations and Best Practices which were created in collaboration with queer and transgender community members across the state to illuminate challenges and opportunities to support LGBTQIA+ communities in Maryland.

Beginning on page 13 of the referenced 2024 Policy Priorities, you will find a section “HIV Prevention and Treatment Access,” which notes the Commission’s concerns that PDAB’s could create unintended consequences and new challenges for patients and entities who dispense medications. Additionally, the Commission notes that several HIV-focused organizations are following the emergence of PDABs across the country, including the Community Access National Network (CANN).

As we address the critical issue of ensuring access to HIV treatment and prevention drugs, it is paramount that we consider the broader societal and structural factors that influence health outcomes. Therefore, we urge the Maryland PDAB to thoroughly assess the social and structural determinants of health in connection with efforts to end the HIV epidemic before evaluating any HIV medication. By doing so, we can better understand the far-reaching implications of our decisions on medication affordability and accessibility, as well as their impact on public health efforts to combat HIV.

The Commission and the Health & Wellness sub-committee are eager to work with the Maryland PDAB to ensure access to HIV treatment and prevention drugs without unintended negative consequences. The Commission has a shared interest with the PDAB to make certain that Marylanders can obtain accessible and affordable lifesaving prescription drugs.

Sincerely,

Jeremy Browning (he/him)
Director
Maryland Commission on LGBTQIA+ Affairs

Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

Biktarvy

2 messages

Mitchell, Anya [redacted]> Tue, Mar 19, 2024 at 10:21 AM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

To whom it may concern,
I'm asking that the Prescription Drug Affordability Board not to consider an HIV drug especially Biktarvy for a cost review. Given the fact that they have not yet clarified what will happen if a drug is deemed unaffordable. The unintended consequences could negatively impact patient access to care which could have severe consequences for people living with HIV.

Anya Mitchell, CPHT
Specialty Pharmacy Liaison – Infectious Disease
MedStar Good Samaritan – Smyth Building
[redacted]

[redacted]

Received. Thank you.
[Quoted te t hidden]

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Park West Health System, Inc.

www.parkwestmed.org

3/20/24

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Members of the Maryland Prescription Drug Affordability Board,

My name is Desiree Lloyd, I am the Client Services Coordinator at Park West Health Systems. I just wanted to express my concern about the medications for cost review specifically the antiretroviral medication Biktarvy used for treatment of HIV.
My concern is the board is considering an HIV drug for a cost review – especially given the fact that the board have not yet clarified what will happen if a drug is deemed unaffordable. The unintended consequences could negatively impact patient access to care which could have severe consequences for people living with HIV.

Please reconsider the medication cost review.

Sincerely,

Desiree Lloyd, LMSW
Park West Health System, Inc.
Hidden Garden Program
Client Services Coordinator
(P) 443-884-7656
(c) 443-326-5763
(f) 443-627-8168

March 20, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council

Dear Members of the Maryland Prescription Drug Affordability Board,

Sanofi appreciates the opportunity to submit comments to the Maryland Prescription Drug Affordability Board ("MDPDAB") regarding its Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council. For the reasons listed below, **we respectfully ask that the Board remove Dupixent® from this list.**[1]

Dupixent, which Sanofi commercializes with its partner, Regeneron, is a biologic medication that blocks the signaling of two key sources of Type 2 inflammation (IL-4 and IL-13) and is currently indicated in the treatment of five conditions: eczema/atopic dermatitis; asthma; nasal polyps; eosinophilic esophagitis; and prurigo nodularis. Given these five indications, Dupixent's utilization is higher than if five separate drugs were developed to treat these conditions – evidence of the value it provides to the healthcare system and to patients. Dupixent was also the first advanced therapeutic approved to treat the majority of its indications, representing transformative scientific breakthroughs for patients suffering from several diseases and is the only approved advanced therapy down to 6 months of age in atopic dermatitis and one year of age in eosinophilic esophagitis. These are additional proof points that demonstrate the value and innovation that Dupixent brings to patients and the healthcare system.

Dupixent was evaluated as part of the drug class used to treat atopic dermatitis by the Institute for Clinical and Economic Review (ICER) at its initial launch in 2017. At that time, ICER found Dupixent's net price to be "well-aligned with the added benefit it provides to patients. Dupilumab represents a good value for money."[2] Since Dupixent's launch, Sanofi has taken reasonable and predictable price increases in line with our Pricing Policy.[3] This is reflected in the fact that

[1] Sanofi reserves the right to supplement this submission with additional information to inform the MDPDAB's decision-making on this important topic.
[2] Institute for Clinical and Economic Review (ICER). (2017). Atopic Dermatitis: An assessment of crisaborole and dupilumab. (2017) (Retrieved from https://icer.org/wp-content/uploads/2020/10/MWCEPAC_AD_RAAG_060817.pdf)
[3] Sanofi Pricing Principles for the U.S. (2024). Sanofi-2024-Pricing-Principles-Report.pdf.

ICER has never included Dupixent, or any other Sanofi medicine, in their annual "Unsupported Price Increase Report." This determination of value at launch, coupled with our commitment to responsible price increases leads to a conclusion that Dupixent remains a good value to patients and to the system.

Dupixent, like all our medicines, is priced to reflect our medicines' value, and our commitment to patient access while minimizing our contribution to health care inflation. To maintain an environment that will continue to bring new healthcare solutions to patients, we must encourage a transition to a value-driven healthcare system that provides incentives for the highest quality care. This evolution will enable both affordable access to treatments and continued investment in medical innovation. Sanofi is committed to helping address this challenge and offers a copay card program for Dupixent patients in Maryland and nationwide to help ensure affordable access to this innovative treatment.[4] With the Dupixent MyWay Copay Card, eligible commercially insured patients may pay as little as $0* copay per fill of Dupixent if they meet the eligibility requirements.[5] Additionally, through the Dupixent Patient Assistance Program, qualified patients with incomes up to 600% of the Federal Poverty Level who are uninsured or whose insurance does not cover Dupixent could receive their medication at no cost.[6]

Additionally, Sanofi asks the MDPDAB to consider that Dupixent's indication for eosinophilic esophagitis was approved as an orphan drug designation. Medicines to treat rare diseases are exempt from certain laws and regulations, as a recognition that a small patient population can only benefit from companies that assume the risks involved in orphan drug development. Other state PDABs, such as Oregon,[7] exempt drugs with orphan indications as well.

Sanofi remains committed – and devotes significant resources – to exploring all of the potential disease states and patient populations that could benefit from Dupixent. A recent clinical trial showed positive results in some patients with chronic obstructive pulmonary disease (COPD) who were treated with Dupixent.[8] We believe that Dupixent will also benefit patients in other potential future indications, and strongly encourage the MDPDAB to consider the potentially chilling effect that a price control could have on this type of innovation. In fact, Dupixent represents precisely the type of innovation and approach to pricing that should be expected from our industry – pursuing first in class or best in class medicines that have the potential to transform the practice of medicine for

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[4] *Eligibility requirements and amount of assistance are subject to change. https://www.dupixent.com/support-savings/copay-card.
[5] https://www.dupixent.com/support-savings/copay-card-enrollment.
[6] https://www.dupixent.com/support-savings/cost-insurance.
[7] Or. Rev. Stat. § 646A.694 (2021).
[8] Bhatt, Surya P., et. al. (2023). Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts. *New England Journal of Medicine*, 389, 205-214. DOI: 10.1056/NEJMoa2303951

patients, and pricing those medicines in a manner that reflects the value they provide to patients and society.

Finally, Sanofi is concerned that the methodology, data sources, and criteria used by the MDPDAB to identify drugs for inclusion in this list was not made available to the public and may not accurately prioritize drugs that pose actual affordability challenges for patients. Additionally, solely targeting the list price of a medicine, which is typically not the price paid to Sanofi, will fail to adequately address patient access and affordability challenges. We encourage the MDPDAB to release the data set relied upon for the generation of this list for specific feedback and consider broader reforms that will make the health care system work better for patients.

Thank you for the opportunity to provide comments and for considering our concerns. We hope that after considering this information, **the Board will remove Dupixent from the list of Potential Drugs for Referral to the Stakeholder Council**.

Please feel free to contact myself or Kathryn Lavriha, Sanofi Sr. Director for State Government Relations, at kathryn.lavriha@sanofi.com or (301) 908-3367 with any questions.

Sincerely,

Deanne Calvert
Vice President and Head, State Government Relations, Sanofi

SINAI HOSPITAL
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Infectious Diseases Ambulatory Center
Department of Medicine
Sinai Hospital of Baltimore
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Baltimore, MD 21215-5271
www.lifebridgehealth.org
410-601-6207
410-601-6006 fax

Baltimore March 20, 2024

Re: The Prescription Drug Affordability Board

To Whom It May Concern,

It is with great interest, and some concern, I have received information about the establishment of the Prescription Drug Affordability Board with the intent of better controlling cost of selected medications. The field of HIV medications is rapidly evolving and many greatly improve medications have reached the market in the past few years, and several more very promising agents are in various stages of development. One of the exciting things with working in the HIV field has been to be able to share the most recent progress with my patients and being able to prescribe modern drugs with improved side effect profiles, reduced pill sizes and increased genetic barriers to resistance altogether improving the health outcomes of people living with HIV and their quality of life. This is a benefit not only for people living with HIV but for the population as a whole.

I am concerned that increased regulation of HIV medications may limit timely access of new, better treatment options reaching this vulnerable patient population. It is also a concern that very few people with direct health care experience and no one with experience of HIV care is on this committee. This lack of insight and direct experience may severely limit the ability to make well informed and balanced decisions in the best interest of patients living with HIV

Please don't hesitate to contact me if you have any further questions.

Sincerely,

Kjell Wiberg, MD
Director Division of Infectious Disease
Sinai Hospital of Baltimore
Hoffberger Building, Suite 17
2435 West Belvedere Avenue
Baltimore, MD 21215
Phone: 410-601-6207
Fax: 410-601-6006