AMERICAN ACCOUNTABILITY FOUNDATION

Research Memorandum

To: Interested Parties
From: American Accountability Foundation
Date: February 20, 2024
Re: Namandje Bumpus COVID and HIV Research

The American Accountability Foundation reviewed the scientific background of Food and Drug Administration Principal Deputy Commissioner Namandje Bumpus. AAF identified **multiple areas of concern**. Primarily, these cover **HIV research designed to enable the riskiest forms of sexual activity** as well as Bumpus' **lockstep approval of the false COVID 'consensus'** (especially concerning the vaccine).

Our review into Bumpus scientific background reveals:

- She obtained *at least $5.3 million in federal funding* for the most graphic aspects of her HIV research.
- She routinely described the COVID vaccine as "safe and effective."
- She downplayed COVID vaccine side effects.
- She referred to the Hispanic community by the pseudo-phrase "Latinx."

HIV Research

Bumpus' medical research primarily focuses on the prevention/treatment of HIV and AIDS. While perhaps well-intentioned, this nevertheless raises several red flags.

Primarily, HIV is a disease that infects a very small portion of the population, albeit one that receives disproportionate attention given the prominence of the LGBTQ lobby in funding liberal politicians.[1] Furthermore, while the disease is tragic for those who suffer from it, it's easy to avoid with obvious behavioral changes.

According to the Centers for Disease Control, AIDS causes 1.5 deaths per 100,000 members of the population[2]. By contrast, Cancer causes 182.4 deaths[3], drug overdoses (primarily, though not exclusively, fentanyl) cause 32.1 deaths[4], and heart disease causes 209.6 deaths[5].

To focus disproportionately on a boutique issue of importance to the LGBTQ base, rather than diseases with applicability to the population at large, suggests, at best, misplaced priorities.

Further, Bumpus' research seems geared toward enabling the riskiest forms of sexual activity.

[1] Washington Post, "'Pink Money' Flowing to Democrats," August 17, 2000.
[2] Centers for Disease Control, FastStats - AIDS and HIV
[3] Centers for Disease Control, FastStats - Cancer
[4] Centers for Disease Control, FastStats - Drug Overdoses
[5] Centers for Disease Control, FastStats - Heart Disease

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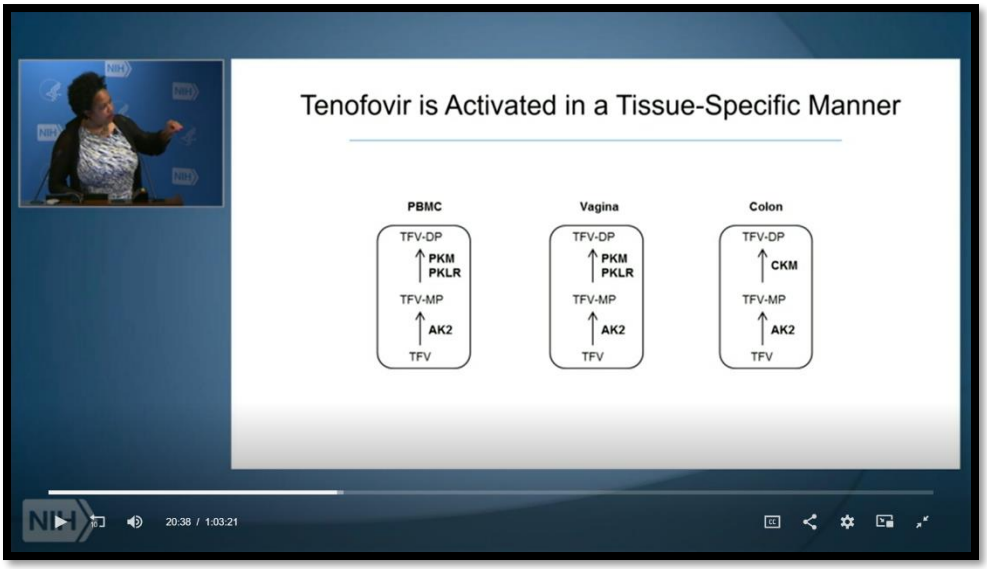
For example, in May 2022, Bumpus spoke to the National Institutes of Health[6], where she made several concerning comments:

- "Social Justice is central to me, and also really central to the identity of my lab." (4:25)
- "Colonic tissue is really an important route to think about because of potential transmission in men who have sex with men…until we can fine tune, and understand, what exposure might be in that [colonic] tissue specifically..." (21:05)

Bumpus' presentation also includes this slide:



At no point in this lecture does Bumpus discuss abstaining from obviously risky forms of sexual activity.

In addition, an examination of academic papers on which Bumpus is listed as a co-author illustrates how her scientific research appears geared towards enabling some of the riskiest forms of sexual activity.

A sample of the article titles (bold text added):

- Tenofovir **Douche** as HIV Pre-Exposure Prophylaxis for **Receptive Anal Intercourse**: Safety, Acceptability, Pharmacokinetics, & Pharmacodynamics[7]

[6] National Institutes for Health,"NIH VideoCast - Toward Personalizing HIV Treatment and Prevention," May 4, 2022.
[7] *The Journal of Infectious Diseases*, "Tenofovir Douche as HIV Pre-Exposure Prophylaxis for Receptive Anal Intercourse: Safety, Acceptability, Pharmacokinetics, & Pharmacodynamics," November 2023

- **Transgender women** on oral HIV pre-exposure prophylaxis have significantly lower tenofovir and emtricitabine concentrations when also taking oestrogen when compared to cisgender men[8]

- Correlation between compartmental tenofovir concentrations and an ex vivo **rectal biopsy model of tissue infectibility** in the RMP-02/MTN-006 phase 1 study.[9]

- Dissimilarities in the metabolism of antiretroviral drugs used in HIV pre-exposure prophylaxis **in colon and vagina tissues**[10]

- Correlation between Compartmental Tenofovir Concentrations and an Ex Vivo **Rectal Biopsy Model of Tissue Infectibility** in the RMP-02/MTN-006 Phase 1 Study[11]

- A Multi-Compartment Single and Multiple Dose Pharmacokinetic Comparison of **Rectally Applied** Tenofovir 1% Gel and Oral Tenofovir Disoproxil Fumarate[12]

- Dissimilarities in the Metabolism of Antiretroviral Drugs used in HIV Pre-exposure Prophylaxis in **Colon and Vagina Tissues**[13]

Taxpayer Funding for HIV Research

Bumpus' efforts to enable risky forms of sexual activity would be questionable enough if it were privately funded. Unfortunately, that's not the case.

AAF reviewed National Institutes of Health (NIH) grants[14] that were disbursed for studies where Bumpus served as principal investigator. We found three projects that received twelve grants, totaling *at least $5.3 million*, geared towards investigating therapeutics that allow individuals to engage in risky forms of sexual activity.

[8] *Journal of the International AIDS Society*, "Transgender women on oral HIV pre-exposure prophylaxis have significantly lower tenofovir and emtricitabine concentrations when also taking oestrogen when compared to cisgender men," November 2019.
[9] *PLOS One*, "Correlation between Compartmental Tenofovir Concentrations and an Ex Vivo Rectal Biopsy Model of Tissue Infectibility in the RMP-02/MTN-006 Phase 1 Study," October 2014.
[10] *Biochemical Pharmacology*, "Dissimilarities in the Metabolism of Antiretroviral Drugs used in HIV Pre-exposure Prophylaxis in Colon and Vagina Tissues," August 2013.
[11] *PLOS ONE*, "Correlation between Compartmental Tenofovir Concentrations and an Ex Vivo Rectal Biopsy Model of Tissue Infectibility in the RMP-02/MTN-006 Phase 1 Study," August 2013.
[12] *PLOS ONE*, "A Multi-Compartment Single and Multiple Dose Pharmacokinetic Comparison of Rectally Applied Tenofovir 1% Gel and Oral Tenofovir Disoproxil Fumarate," October 2014.
[13] *Biochemical Pharmacology*, "Dissimilarities in the Metabolism of Antiretroviral Drugs used in HIV Pre-exposure Prophylaxis in Colon and Vagina Tissues," August 2013.
[14] National Institutes of Health, Reporter, "Namandje N. Bumpus" Accessed February 12, 2024.

Project	Public Health Relevance Statement	FY	FY Total Cost	Project	Sub Project
Developmental Pharmacology of Antiretroviral Metabolism in Mucosal Tissues	Project narrative – Tenofovir is a drug used to treat and prevent HIV infection, that requires activation by proteins inside of cells in order to be efficacious. The goal of this project is to determine whether tenofovir is activated differently in adolescent tissue as compared to adults and to investigate whether hormonal changes during development might impact tenofovir activation. **These studies are expected to improve the rational selection and dosing of anti-HIV drugs in adolescents.**	2017	$517,236	1R01AI128781-01	
		2018	$443,424	5R01AI128781-02	
		2019	$342,560	5R01AI128781-03	
		2020	$342,560	5R01AI128781-04	
Drug Phosphorylation and Aging	Adenylate kinases play a central role in maintaining cellular homeostasis. They are also able to activate certain drugs via phosphorylation. The goal of this project is to investigate the impact of aging on drug phosphorylation, and adenylate kinase levels and activity. This work aims to advance mechanistic understanding of the pharmacology of aging.	2020	$555,596	1R01AG064908-01A1	
		2020	$125,000	3R01AG064908-01A1S1	
		2021	$555,596	5R01AG064908-02	
Tissue pharmacology imaging and modeling	PROJECT NARRATIVE This unprecedented methodology has broad relevance to improving rectal and also vaginal drug delivery - for topical and systemically acting molecules (e.g. prophylactics, therapeutics, contraceptives, etc.). It enhances our understanding of the drug delivery process, and provides experimental and computational methods that will foster improved, rational design and performance evaluation of new products.	2014	$539,411	1U19AI113127-01	6596
		2015	$523,808	5U19AI113127-02	6596
		2016	$542,099	5U19AI113127-03	6596
		2017	$596,337	5U19AI113127-04	6596
		2018	$270,323	5U19AI113127-05	6596
		Total	**$5,353,950**		

Below we examine these three projects in greater detail.

Investigated HIV Antiretroviral Activity in the Vaginal and Colorectal Tissues of Adolescents

While at Johns Hopkins University, Namandje Bumpus served as principal investigator for a study to investigate whether antiretrovirals work differently in the mucosal tissues (vaginal and colorectal tissues) of adolescents than they do in adults. This work received $1.65 million in NIH funding over four fiscal years.

The abstract for the study noted that "vaginal and colorectal tissues are putative sites of pharmacological activity" for antiretrovirals and that a goal of the study is to "identify the nucleotide kinases that phosphorylate TFV in adolescent vaginal and colorectal tissue".[15]

> *Tenofovir (TFV) and other nucleotide reverse transcriptase inhibitors must be activated via phosphorylation by intracellular nucleotide kinases in order to become pharmacologically active. While the kinases that activate TFV in mucosal tissues in adults have been identified, studies have not been performed to determine which enzymes phosphorylate TFV in adolescents. Further, whether hormonal changes during development might impact the expression and activity of the kinases that have thus far been demonstrated to activate TFV hasn't been explored.*

[15] NIH RePORTER, "Developmental Pharmacology of Antiretroviral Metabolism in Mucosal Tissues," Project Number 1R01AI128781-01

> *Gaining a mechanistic understanding of the expression patterns and regulation of these nucleotide kinases across developmental stages in mucosal tissues is of particular importance within the context of using these drugs for* ***HIV pre-exposure prophylaxis since vaginal and colorectal tissues are putative sites of pharmacological activity*** *in this setting. With this in mind, the goals of this proposal are to identify the nucleotide kinases that phosphorylate TFV in* ***adolescent vaginal and colorectal tissue*** *and to probe the effects of hormones that govern developmental maturation on TFV disposition. The aims are as follows: (1) determine which kinases activate TFV in adolescent tissue; the expression pattern of nucleotide kinases in adolescent vaginal and colorectal tissue will be established using proteomics-based approaches; knockdown of identified kinases will facilitate identification of those that exhibit activity toward TFV in tissue; (2) test whether TFV activation and TFV distribution in tissue are hormonally regulated; nucleotide kinase expression will be measured in response to developmental hormones and mechanisms of hormonal regulation will be probed; MALDI-mass spectrometry imaging will be employed in order to visualize the distribution of TFV as well as phosphorylated metabolites of TFV in adolescents versus adults. It is expected that the completion of the proposed studies will provide a mechanistic foundation for the rational selection and dosing of antiretrovirals for* ***HIV pre-exposure prophylaxis in adolescents.***

While no in vivo studies were done in human adolescents relating to this work (the study instead used in vitro research and mice experiments), it is concerning that Bumpus received federal funding to engage in research that ultimately seeks to optimize HIV pre-exposure prophylaxis dosing in adolescents, so that they may engage in high-risk sexual activity.

Received $1.2 Million in Federal Funding to Investigate HIV Antiretroviral Activity in Colorectal Tissue of Older Versus Younger Adults

Across three fiscal years, Namandje Bumpus served a principal investigator of a Johns Hopkins University study that received over $1.23 million in NIH grants to investigate HIV antiretroviral activity in the colorectal tissue of older adults vs younger adults. The abstract from the study, titled "Drug Phosphorylation and Aging" is below:[16]

> *Adenylate kinase 2 (AK2) is a key regulator of cellular homeostasis via the interconversion of adenine nucleotides ATP, ADP, and AMP. We recently demonstrated that AK2 plays a crucial role in the activation of the antiretroviral drug tenofovir (TFV) in cells and tissues that are putative sites of HIV infection. TFV is a nucleotide reverse transcriptase inhibitor that is prescribed as a tenofovir disoproxil prodrug in combination with other drugs for the treatment of HIV. TFV requires two sequential phosphorylation steps in order to become pharmacologically active. Tenofovir disoproxil is also a component of the only FDA approved HIV pre-exposure prophylaxis (PrEP) regimen. The identification of AK2 as a TFV-activating kinase spurred us to sequence the human genomic DNA of ~1200 individuals and identify AK2 genetic variants that could impact TFV activation. Thus far, in vitro studies have revealed that several of these variants do indeed impact AK2 activity towards TFV. In moving forward, an effect of aging on AK2 expression and activity will be tested specifically. Determining whether the activity of TFV- activating kinases, particularly AK2, could exhibit differential activity in older versus younger adults is of importance since older adults (≥50 years of age) account for an approximate 17% of new HIV infections annually. The aims of this proposal are to: 1) test the hypothesis that AK2 is the primary AK enzyme involved in the phosphorylation of TFV. We will silence the expression of each of the 9 individual AK*

[16] NIH RePORTER, "Drug Phosphorylation and Aging," Project Number 1R01AG064908-01A1

> *enzymes in cultured CD4+ cells using a CRISPR/Cas9 system and test for activity towards TFV. In addition, AK enzymes will be cDNA- expressed and purified to test for their activities. Biophysical approaches will be applied in order to gain an understanding of binding affinity. Further, we will test the impact of age-related modifications on AK2 expression and activity; 2) test the hypothesis that the patterns and activity of kinases that activate TFV differ between older adults (ages 65-80) and younger (ages 18-30) adults in circulating CD4+ T cells and CD4+ T cells that reside in colorectal tissue. In addition, we will test whether activation of TFV in older adults differs from that of younger adults following oral dosing with tenofovir disoproxil, via characterization of the levels of phosphorylated TFV in circulating and colorectal tissue resident CD4+ T cells. MALDI-mass spectrometry imaging will be employed to visualize the distribution of phosphorylated TFV in colorectal tissue CD4+ T cells of older versus younger adults.*

Again, it is concerning that Namandje Bumpus received significant federal funding and spent a disproportionate amount of her research efforts on projects relating to individuals that engage in high-risk sexual activity.

Received $2.4 Million to Investigate Microbicide Activity in Colorectal Tissue to Help Design "Best Microbicide Enema"

In a study titled "Tissue Pharmacology Imaging and Modeling," Namandje Bumpus served as the principal investigator of a sub-project relating to investigating drug delivery in rectal and vaginal tissues. The study received $2.47 million in NIH grants over five fiscal years.

The abstract of the study is below:[17]

> *PROJECT 3 (TISSUE MODELING PROJECT) - PROJECT SUMMARY A successful microbicide product has pharmacokinetics (PK) that effect prophylactic pharmacodynamics (PD). Product design should manipulate candidate compositions, volumes, and drug packaging in a rational manner to yield target PK/PD; but we have limited understanding of this relationship. Further, our methods for experimentally evaluating PK in animals and humans are limited: they do not delineate drug concentration distributions throughout target compartments where the drugs act, and may miss drug partitioning and concentration gradients that drive drug transport; they fail to measure key molecules, e.g. drug metabolites, HIV, and intracellular molecules that might modulate drug efficacy (e.g. endogenous nucleotides). Thus, drug concentrations in contemporary PK studies, while useful, do not adequately inform us about product PK and may not accurately reflect true prophylactic potential. Project 3 will develop and apply new methodology - experimental and computational - to understand and predict these critical, heretofore missing elements of PK, for the enema microbicide product, as it is being designed and evaluated by the DREAM Program. Our team has synergistic expertise in both experimental methods and computational modeling of the kind needed here. Aims 1 and 3 develop this unprecedented, transformative methodology. Aim 1 integrates detailed MALDI measurements of drug, metabolite and other key molecules in colorectal tissue specimens with those by a specialized instrument that applies confocal Raman spectroscopy - to measure local microbicide drug concentrations in tissue specimens in 3D - coupled to spectral domain optical coherence tomography - to link drug concentration to structures of the mucosal tissue within which drug is migrating. Aim 3 creates a new biophysics and physiology based computational compartmental model of detailed PK for enema designs. It predicts the 3D, time-dependent drug concentration distributions in these compartments - delineating PK with greater resolution than previously*

[17] NIH RePORTER, "Tissue pharmacology imaging and modeling," Parent Project Number 1U19AI113127-01, Sub-Project ID 6596

possible. Aims 2 and 4 and apply the methods of Aims 1 and 3 to the human studies in Project 1 and 4 and NHP studies in Project 2, helping interpret PK and PD data, and thence understand, design and choose the best microbicide enema designs.

COVID

During the height COVID pandemic, before she was employed by the federal government, Namandje Bumpus gave several interviews where she made claims related to masking, social distancing, and COVID vaccines that have not stood the test of time.

On February 3rd, 2021[18], Bumpus asserted the COVID vaccine was "innovative" (0:29) and that side effects were "mostly mild to moderate" (2:58).

Later that month[19], Bumpus released a video where she made several dubious claims in less than three minutes.

- "The great thing about the mRNA technology that these vaccines use, is that it can be nimble, so that we can actually deliver these genetic instructions to make some of these variants instead." (1:44)
- "Even discussion of a booster, potentially, that would be specifically for making our immune system respond to the variant." (1:52)
- "This vaccine technology allows us to specifically address variants as they emerge." (2:00)
- "This is why getting vaccinated, and following all of our social distancing measures, masking, handwashing are particularly important." (2:18)
- "If we can use everything in our toolkit, the vaccines, our handwashing, our distancing, staying away from large groups of people, then we're more likely to reduce the transmission of the virus and the variants won't be able to persist." (2:38)

In March 2021[20], Bumpus appeared on a panel with the CBS news affiliate in Washington DC where she continued to carry water for the COVID vaccine. Most notably, she called the vaccine "safe and effective" several times. She also refers to the Hispanic community by the psuedo-phrase "latinx."

- Johnson and Johnson vaccine: "These vaccines work and they're **safe and effective**." (2:46)
    - A month later: FDA Adds New Warning to Johnson & Johnson's COVID-19 Vaccine Fact Sheet (carefirst.com)
- "These vaccines are all **safe and effective**." (3:28)
- "You should get vaccinated even if you've had COVID 19." (10:35)
- "We still need to remain vigilant about [social] distancing and masking." (21:21)

[18] YouTube, "Covid-19 Story Tip: Namandje Bumpus, Ph.D.: What We Know About the COVID-19 Vaccine," February 3, 2021.
[19] YouTube, "Namandje Bumpus COVID Variants," February 17, 2021.
[20] YouTube, "VACCINE Q&A: Five top doctors answer your COVID-19 questions," March 5, 2021.

- "Definitely maintaining masking, and distancing, and handwashing...particularly in public, we're learning more about the potential for transmission. So, um, yes." (28:08)
- One of the other panelists makes a comment about "vaccine inequity" with which Bumpus will run in the next point.
- "I agree with that and I think it's really important that point that you made [unintelligible] about access. Cuz there's a lot of talk, you know, about Black, **LATINX**, and indigenous people and hesitancy. Certainly, we know that exists, and [unintelligible]. But the folks who want it can't get access and that's a problem. And we know people are more likely to get vaccinated when they know people who've been vaccinated. So, access is what we really need to focus on, I think, certainly education, we need [unintelligible] access." (54:11)
- In response to a question about the Johnson and Johnson vaccine: "**Safe and effective**, I said, I mean, the studies showed that prevented hospitalization, prevented death, and a substantial decrease, you know 85 percent decrease in our severe cases, and still effective even looking at mild cases of COVID 19. We can't compare these things directly, so I said earlier, we can't compare these numbers and efficacy rates, they were just done at different times during the pandemic, different people, different locations. But on top of that, they work different ways, so the idea of one dose, two dose, it's really related to how well they work, and we've seen that work, so now, that's, we're rolling out, but I really wouldn't make the comparison and say that because something's one dose it's not as good as two. They're different vaccines and they actually do work." (56:24)
- "The vaccines are **safe and effective**. And that's probably that we're hearing the opposite online, you know, that the mRNA is bad for you because mutates your own DNA. mRNA is part of us, it's natural, and the vaccines are [unintelligible]." (1:00:41)

That April, Bumpus told Reuters,[21] "**[t]he safety and efficacy of COVID-19 vaccines currently in use have been rigorously tested**, and the trials did not skip any steps."

Beyond COVID, Bumpus' repeated insistence that the vaccine was "safe and effective" raises concerns regarding her ability to fulfill the FDA's broader mission of pharmaceutical industry oversight. If she failed to understand the risks on such a high-profile endeavor, how can the American people trust her judgement across the plethora of drugs the FDA regulates?

For all these reasons, AAF has significant concerns about elevating Namandje Bumpus to the #2 position at the FDA.

[21] Reuters, "Vaccine trials were not rushed; possible link to extremely rare blood clots is unlikely to be detected in trials ," April 22, 2021.