

AIDS ACTION BALTIMORE, INC.

14 EAST EAGER STREET, BALTIMORE, MARYLAND 21202 (410) 837-2437 FAX (410) 837-2438
BaltoAIDS@aol.com www.aidsactionbaltimore.org

July 30, 2020

Francis S. Collins, MD, PhD
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

We, the undersigned organizations, urge you to ensure that the sponsors of COVID-19 clinical trials for COVID-19 treatment and prevention interventions do not exclude people living with HIV. Our letter is occasioned by the exclusion of people with HIV in the mRNA-1273 Moderna Phase 3 COVID-19 vaccine trial according to [ClinicalTrials.Gov](https://www.clinicaltrials.gov). We are extremely dismayed to learn that a COVID-19 vaccine candidate developed with significant contributions from researchers at the NIH excludes people with HIV with no scientific basis. We want to be sure you are aware of this situation, will do everything in your power to intercede with Moderna to reverse this exclusion and ensure that such an exclusion never happens again. This matter is particularly urgent and requires your immediate attention as this trial opened to enrollment on July 27, 2020.

The Moderna mRNA-1273 [exclusion criteria](#) specifically cites people with “human immunodeficiency virus (HIV) infection.” This sets a terrible precedent, not grounded in any scientific data. If the Moderna vaccine is approved by the FDA, there will be no data on its safety or efficacy in people with HIV. Thus, there will probably not be an FDA indication for people with HIV or payer reimbursement as a result.

Although the inclusion criteria notes that adults with pre-existing medical conditions who are in stable condition are eligible, the fact that HIV is specifically stated in the exclusion criteria without further information infers that the note for adults with pre-existing medical conditions does not apply to them regardless of their health status. This must be clarified in all publicly available information for the Moderna trial with the protocol team and with all participating trial sites as well as on [ClinicalTrials.gov](https://www.clinicaltrials.gov).

There is no clinical justification for excluding people with HIV from COVID-19 vaccine trials. Thanks to the advent of triple combination antiretroviral therapy (ART) in the mid-1990s, HIV infection has not been synonymous with an “immunodeficient state” for over two decades. For this reason, routine immunizations are recommended for people with HIV, with the only caveat being withholding of certain live vaccines if the CD4 T cell count is below 200, [according to the CDC](#).

At most, CD4 T cell threshold criteria might be employed if there are concerns about people with very low counts being able to mount insufficient vaccine responses. If there are concerns about a unique immune response for people with HIV, this can be studied through a subset analysis of participants with HIV. This approach should be considered for participants with other controlled co-morbidities, and is especially important with respect to communities of color who are disproportionately affected and suffer disparate outcomes from both HIV and SARs-CoV-2 infections.

Our positions are supported by the June 2020 FDA's [Development and Licensure of Vaccines to Prevent COVID-19](#) Guidance for Industry which provides in pertinent part on page 11:

“Evaluation and vaccine safety and efficacy in late phase clinical development in adults should include adequate representation of elderly individuals and individuals with medical comorbidities.”

Enrollment in COVID-19 clinical trials, including vaccine trials must reflect the populations who have been most impacted by COVID-19, especially communities of color who are experiencing both disproportionate SARS-CoV-2 infections and disparate COVID-19 outcomes. [Polling indicates](#) that just 50% of Americans plan to get a COVID-19 vaccine when one becomes available, with just 25% of Black/African Americans and 37% of Latinx reporting that they plan to get a vaccine when available. To build trust and avoid policies that can compromise trials, such as the exclusion of people with HIV or other populations, community representatives must be involved in COVID-19 clinical trials design and development from the onset, not only engaged to further study recruitment.

All COVID-19 clinical trial sponsors must be held to this critical standard if they are to be successful in delivering effective treatment and prevention interventions expeditiously. The NIH is in a perfect position to explain to sponsors that we will need community trust in order to accrue trials and develop products the US population will not be afraid to actually take after FDA approval. NIAID has had an excellent record of drug development community engagement success which has benefitted all HIV stakeholders, and which has been translated to models for other diseases.

The HIV community was promised that there would be community representation in all aspects of COVID-19 clinical trials development. But all we see is procrastination which now appears to be purposeful. Many of us surmised that community involvement would occur via the already established NIAID Community Advisory Board (CAB) networks which are already in place and well-established with seasoned committed members with many years of dedicated service. There is no good reason why these CABs cannot be utilized and provided adequate funding until the NIH can constitute COVID-19 CABs.

Unfortunately, we have learned that you intend to create community engagement structures for COVID-19 and all other diseases. What we do not need here is another level of underfunded bureaucracy which will take who knows how long to implement. This is an urgent matter, just as urgent as every other aspect of COVID-19 drug treatment and prevention intervention development. We need COVID-19 community engagement NOW! If there had been community participation in the development of the mRNA-1273 vaccine trial, we seriously doubt that we would find ourselves in this untenable predicament.

Further, even though there have been a number of nominations sent to the COVID-19 Guidelines Panel, to date all candidates have been rejected. We are also hearing that Moderna and Operation Warp Speed members are adverse to any community involvement. This unwise pattern of conduct reeks of community exclusions and promotes distrust which will adversely affect COVID-19 recruitment goals and intervention acceptance after FDA approval. This is particularly true in the vaccine arena.

While we understand the unprecedented urgency of the COVID-19 global health crisis and appreciate the necessity of advancing COVID-19 clinical trials without delay, the effectiveness of COVID-19 treatment and prevention interventions will be significantly diminished if they are not widely accepted by individuals in the U.S. and globally, and studied in diverse populations, especially communities of color who need them the most. There are approximately 38 million people living with HIV globally, 25 million of whom are on antiretroviral therapy. They have an important role to play in clinical trials. We

must understand their response to COVID-19 treatment and prevention interventions. To exclude people with HIV from the first US Phase 3 COVID-19 trial with an n of 30,000 people based on no scientific justification is unconscionable.

We again urge you to intercede with Moderna to ensure that people with HIV are not excluded from the current their Phase 3 mRNA-1273 trial, and assure us that you will do everything in your power to ensure that no future COVID-19 vaccine trials or other treatment or prevention trials exclude people with HIV. Please also share your plan to ensure communities of color and people with HIV are enrolled in US clinical trials and involved in community engagement regarding not only recruitment efforts, but also in trust promoting clinical trial design issues and protocol development.

Thank you for your essential work and your commitment to the HIV and SARS-CoV-2 pandemics. Your time and efforts are greatly appreciated. We look forward to your prompt response.

Yours truly,

Lynda Dee, AIDS Action Baltimore

Mark Harrington, Treatment Action Group

Richard Jefferys, Treatment Action Group

Guillermo Chacon, Latino AIDS Commission

Moises Agosto, National Minority AIDS Council

Murray Penner, AIDS Treatment Activists Coalition

Mitchell Warren, AVAC

Nelson Vergel, PoWeR USA

Peter Staley, PrEP4All

AIDS United

The AIDS Institute

Black AIDS Institute

Jeff Taylor, HIV+ Aging Research Project

Jeff Berry, Test Positive Aware Network

Gregg Gonsalves, Yale School of Public Health

Derrick Mapp, CoVPN Community Representative

Bruce Richman, Prevention Access Campaign

Asia Russell, Health GAP

San Francisco AIDS Foundation

Simon Collins, HIV i-Base

Alex Sparrowhawk, UK CAB

Ricardo Fernandes, European AIDS Treatment Group

Carl Baker, Desert AIDS Project

Krista Martel, The Well Project

Aaron Fox, Los Angeles LGBT Center
Martin Delaney Collaboratory Dare CAB
Michael Louella, defeat HIV CAB
Adam Ehm, Living Positive, Victoria, AU
Positive Women's Network, Oakland, CA
INSIGHT Clinical Trials Network Community Advisory Board (CAB), Minneapolis, MN
The Reunion Project, Chicago, IL
SisterLove, Atlanta, GA
PFLAG National, Washington, DC
Asociacion Vihsibles
WORLD, Oakland, CA
NASTAD (National Alliance of State and Territorial AIDS Directors)
Laurie Sylla, Mountain West AETC
Grupo de Trabajo sobre Tratamientos del VIH (gTt-VIH)
Howard Brown Health, Chicago, IL
AIDS Foundation Chicago, Chicago, IL
LA Women's HIV AIDS Task Force
AIDS Research Consortium of Atlanta, Atlanta, GA
Iris House, New York, New York
Association of Nurses in AIDS Care
International Association of Providers of AIDS Care
IRMA - International Rectal Microbicide Advocates
Siegfried Schwarze, Projekt Information e.V.
Fred Schaich, International Foundation for Alternative Research in AIDS
Coordinador Estatal de VIH-Sida
Grupo de Trabajo sobre Tratamientos del VIH (gTt-VIH)
New Queers on the Block
North Carolina AIDS Action Network
UNC CARE Community Advisory Board
Zephyr LTNP Foundation, Inc.
MPact Global Action for Gay Men's Health and Rights
Projecte dels NOMS-Hispanosida
Projeckt Information e. V.
Matthew Rose

Mark Milano
Jim Pickett
Wim Vandeveldel
Alberto González
Matt Chappell
Tonia Poteat, PhD, MPH, PA-C
Karine Dube
Danielle Campbell
Christopher Roebuck
Alejandro Sarmiento
Andrés Medina
Antonio
Brandon Consuegra
Carlos Gutiérrez
Michelle Lopez
Cristian González
Daniel Alejandro Pérez Henao
David Lorca Asís
David Munroe
Peter W. Hunt, MD
Elena Esteban
Elizabeth Glaser
Felipe Acevedo
GALACTYCO
Independent Access to Affordable Medicines Advocate
Jerry Kane
Jesús David Hernández Daguer
Jhonatan Jiménez
Jhonny Coronado
Joan Tallada
José Leonardo Mujica Quintero
Jose M. Zuniga, PhD, MPH
Jose Rioja
Jossy Davila

Juan Gerardino
Juan Manuel Posso Gómez
Juan Sebastian Rubiano Sánchez
Juan Sebastián Vanegas
Levi Marun
Liang Mateos
Liliana Reyes Juárez
Lupicinio Iñiguez-Rueda
Manuel Luis
Martin Quispe Lope
MásQueTresLetras
Michael Manganiello
Michael Plankey, Phd
Miguel Perez
Rafael Cardona
Ricardo Sandino López
Rodrigo Caballero
Ronald Steven Gonzalez Carreño
Sindy
Ron Cockrell
Colum Ohare
John McLay
Philip Stover
Peter Solan
Jose Valdez
Elizar Funtilon
Jeff Sheehy
Tom Eickleberry
Ron Kudrako
Liam Sauer-Wooden
Tim Murphy
Damon McLay
Mitchell Mathias
Danny Holt

Carl Harris (He / Him)

Michael Luciano

Justin Waddell

Mack Mcquade

Jeffrey Jenne

Mark Dunkum

Krista Martel

Blaine Haws

Gregor Kalfas

William Hall

George Thompson

Gary Lawrence

Jesus Lopez

LoisPetty

Dr. Robert Wood

Mark Lindsey

Lewis Mendoza

Starlett Mahoney

Michael Ackil

Bruce Ward

Jerome Gillespie

Bonnie Warburton

David Carpenter

Rand McClain

Jesse Wellmeier

Mack Hicks

Ed Ferriter

Badre Khiara

Julian Garces

Dave Hall

Didier Piot, MD

Thomas Tripp

Andres Ferrer

Steven Moore

Joross de Vera
Robinson Bustos
Chad Kenney
Shelby Ferris
Alvaro Fuentes
Larry Johns
Cristian Reynoso-Betancourt
Howard Grossman
Dominga Lorenzo
Karl Schmid
William Ball
Greg Bradfield
Floyd Bromley-Spiegle
Pedro Ramos
Luiz Avina
larry wadsworth
Teryl Stickney
John Butler
Mark Troy
Julene Weaver
Lesster Munguia
Emma Mills
Debbie Oatman
brianna amador
A. K.
Vanessa Mendoza
Maddie Byers
Crystal Moles
Alda Ferreira
Guillermo Velez
Michael Garrett
Benjamin Heim shepard
Terry Frick
Cheriko Boone

Joan Roney
Andres Garcia
Richard Bracciodieta
Michael Montalbano
Emily McCave
Daniel Rodgers
Gregory Smith
Sylvia Mata
Yash patel
Angela Hawkins
Arianna Marie Claveria
Ann Lee
Delta Likins
Daniel Likins
Amy Siwik
Chris Camp
Lisa White
Roger Crowe
Mark Stanger
Jenny Wagner
Cara Dodge
Karen Robinson
Nancy Ahn
Leo Sapienza
Marcela H
Amelia Shelly
Sarah Nason
Jessie Read
Samson Harman
C. W.
Miranda Cutler
Elizabeth Moule
Isabella Martinez
William Lopez

Rachel Berks
Gisell Chacon
Clint Bump
Hailey Austin
Michael Espinoza
Zechariah Hillyard
Amira Goble
Samuel Bett
Megan Fresh
Kate Elling
Luis Menera
Mark Milano
Lisa Carr
Dan Hart
Robert Pedroso
Mark Marquez
Cathy Stilwell
Jeffrey Holman
Donna Neves
Katya Holmes
Kerry Purtill
Adam Harley
Dirk Hibler
Kim Chinh
Victor Garay
José Alfredo Ávila
Chris Allen
James Hibbins
Marcus McPherson
Robert Stubblefield
Jennifer Royall
Emma Harley
Connor McMahon
Robert Ettinger

Michael Golk
Angelo Spicuzza
Robert Toth
Drew Sisselman
Jorge Urquijo
Waldon Adams
Andrena Ingram
Kevin Gala
Jesse Rabinowitz
Lakeeta Daniels
David Lynch
A.L. Steiner
Larry Fenderson
George Fine
Erik Moreno
Paul Peterson
George Carter
Roy Bayardo
Donny Daniels
Hector Ruiz
Max Harley
Gustavo Rios
Todd Shea
Garrick Gondo
Lacey Nagar
Edward Rewolinski, Ph.D.
Gary Ross-Reynolds
William Mejías Navarro
Cameron Kinker
Timothy Kopischke
Megan Khaerisman
Thomas Reed III
Kendra Rossi
Butch McKay

Timothy Baker
Sydni Neves
E. Aries
Jeffery Larson
Tim Menza
Octavio J Vallejo Vallejo Aguilar
Victoria Chinnell
David Bruce
Paulo Arriola-Headley
Kirsten Felix
Martha Stanley
G. Davis
Christy Respress
Sarah Calderon
Katie Farrar
Jesús Geliga Vargas
Patrick Gallagher
Brandon Griewank
Daniel Lamoureux
Joan Whittaker
Donald Eklund
Megan Bloom
Harry Davis
Marilyn Mora
Michele Lott
Sharon Sinton
Mark Laycock
Wade Schaerer
David beck
Adam Biolchin
Jen Bathelt
Paul Hawkins
Christopher Morot
Michael Rowley

Olimpia Diaz
Antonio Tanner
Tony Collado
Jose Castellanos
Solomon Berhe
Perry A. Lannaconi, Jr.
Mya Morrow
Matthew Reynolds
Andres Martinez
Samuel Daylor
Robert Ballance
Alejandra Grillo
Siddharth Bhattacharyya
Jen Balkus
Nikhil Bhardwaj
Liudan Martínez
Ivan Garcia
David Cohen
Jeffrey Schouten
M. Boykin
Catherine Kaufmann
Mike Murphy
Charles Medina
Carin Enovijas
Raul Robles
Paul Esposito
Stephen Allen
Cassandra Baim
A. Garvin
Tana Pradia
Oscar Sweeney
Sam Raine
Michael Vendl
Daniel Szymczyk

Carol Leigh
Matthew Durstenfeld
Kate Elder
Sajib Biswas
Kevin Maloney
Amani Penrow
Heather Embree
Tim Nedoba
Christopher Gilkey
Brigette Oestreich
Kathleen Cruz
Glenn Giuttari
Juan Porter
Russell Campbell
Sheila Mondello
Gregory Story
Paul Aguilar
Nena Walby
Tony Alvarez
McKinley Adams
Harley Cox
Janeen Rojas
Duane Bandel
William Dannie Lane
Cherri Watson
Steven Goldsmith
William Rynearson
Nina Askew
Veritee Reed Hall
Daymien Kaiser
Henry Perry
Jorge Serrato
Brad Marine
Steve Lewis

John Dennis
Valerie Brenes
Cristal Moreno
Cole Coughlin
Lee Chandler
Thomas Hagerty
David McCleve
Patty Reardon
Diana Reaume
Matthew Osgood
Olivia Sposato
Mark Williams
Erick Okioma
Victoria Noe
Alena K.
Mark Grantham
Gary Boots
James Plunkett
Edmond Yomtoob
Jamie Schield
John Reams
Jax Kelly
Veda Pippin
Zariah Tolbert
Lorne James
Marco Salinas
Keenan Burton
James Powers
John Phelps
Cris Santo
Scott Sawyer
Shaun Behr
Marlene Davis
John Abbott

Tamra Armour
Phillip Diers
Roger Cunha
Doc Duhon
Will Wilson
Teto Prieg
Rosemary Musandipa
John Yarlett
James Hernandez
Josh Cabal
Mary Cavanaugh
Chris Bentley
Emily McGowan
Linda Smith
Josi Hodge
Dona Kirkpatrick
Cheryl Howe
Jay Blount
Ryan Mckenna
Cristal Santos
Nathan Facticeau
Mark S. King
Chris Kenyon
Catie Read
Nevaeh Anderson
Albert Benson
Melissa Kirkman
Rachel Patterson
Hanh Thuc Nguyen
Tayler Martin
Deborah Wolk
Nidhi Patel
Leo Ryan-Schaffner
Brian Tucker

Boone Che
Ower Oberto
Elsie Adams
Doug Smith
Ariana Copas
Paul Haugen
Tracey Cramer
Joseph Boman
Damaris Cruz
Peter Santiago
Timothy Jackson
Aknor Birk
Jay Vithalani
Michael Thorstensen
James McAllister
Alejandro Urquides
Juan Maya
Eric Crow
Malcolm Brown
Troy Phillip
Sebo Marobela
Artie Jordan
Dzibaidzo Chihambakwe
Daniel Agusti
Didint Prehantoro
Janos Balog
PRIZILA VIDAL
Peter Suhai
Frank Rodenbourg
Mary Mans
Bethany Ionta
Maxx Boykin
Bebedic Bataluna
Ashwin Singh

Tina Weaver
Jamie Arangure
Steven Poyner
Robert White
Lefran Lloyd
Julie Pieper
William Thompson
Gabrielle Manigault
Angela Hird
David Morris
Timothy Leslie
Harold Holler
Jason S
Greg Vick
Darwin Carlson
Daniel Drummond
Thomas Novak
Randal Startz
Barbara Hengemihle
James Stacy
Ernest Berardinelli
Sergio Atocha
Steven Solomon
Ruth Velazquez
Paul Marshall
Colin Corbett
Karyn Waxman
Mark Beauchamp
Gerard Marinus Hiddink
Richard Baird
Sandra Brown
Rick Bassett
Ar Warren
Keith Setzer

Proscovia Ayoo
Michael Hays
T Richard Corcoran
Daniel Green
Linda Frascilla
Tommy Schmidt
Laki Angela
Tim Williams
George Jr
Judith Shaw
Terrence Donovan
Doug Vincent
Thomas Villa
Gianna Jade del Vecchio
Barbara Finbloom
Shahiema Ryklief
Joseph Diaz
Jean Adie
James Oakes
Ed Barron
Cristian Cifuentes
Katrina Jacobus
Chances Theap
Rodney Douglas
Asabe Fatima Ibrahim Ibrahim
Marci Laird
Emanuel Ndawo
Sedick Dawood
Diego Celaran herreros
Stephanie Manzi
Jeff Moore
Jordi Piqué
Lelia Pendleton
antonio alba

Raul Herrera
Rossy Olguín
Michael Mueller
Eneko Gutierrez
Lloyd Blevins
Miguel Vazquez
Scott Self
Moises Torres
Guy Piscione
RAUL ESTEBAN VALENCIA GIL
Rodney Tucker
Cayetana gomez
Chis McFarland
Steve Hornsby
Conchi Hernandez
María Natalia Sáenz Agudelo
saioa uribeetxebarria
Juan Pablo Soto Araque
Edgar Galicia
Jordi Piqué
Lelia Pendleton
Antonio Alba
Raul Herrera
Rossy Olguín
Michael Mueller
Eneko Gutierrez
Lloyd Blevins
Miguel Vazquez
Scott Self
Moises Torres
Guy Piscione
RAUL ESTEBAN VALENCIA GIL
Rodney Tucker
Cayetana gomez

Chus McFarland
Steve Hornsby
Conchi Hernandez
María Natalia Sáenz Agudelo
saioa uribeetxebarria
Juan Pablo Soto Araque
Brian Preston
Leidy Maryori Mona pulqarin
Douglas Long
Masedi Thata Kewamodimo
Marc Lugo
Levon Barrett
Maribel Fernández Carbonero
Gabriel Suarez
AH Alvarez
Age Jay
José Carlos Salcedo
Tommi Tate
Juanse Hernández
Landon Yamaoka
Gladys Olguin
Brito Alejandro
M^aLuisa Fernandez
B A Wellman
Peter Accardi
ROBERTO HERMIDA
Thomas (T.J.) Lee-Miyaki
Susanna Martin
Jordi Diez
Nicholas McKay
RONALD ARAGON
Nicholas Sharbo
Joe Bullock
Hank Trout

Ivan Castro Rivadeneyra
José García
Alejandro Gómez Pasco
Juno Rosenhaus
Mandy Fire
Mariano Gomez
Thomas Luger
Dan DeWitt
Orbit Clanton
Carlos Romero Prieto
Antonio Poveda
Wokie Cole
Chris Rico
Manuel Gómez Ortega
Héctor Hugo Álvarez Castellón
Garrett Smith
Benjamin Smith
Laura Smith
Nina Martinez
Gregory Smith
Mark Misrok
Tim T Sliger
Maria Carmen Martín García
Agustin Delgado
Lorean Walls
John Boucher
Giovanna Valls
Duván Rodríguez
Joanna García
Juan Pablo Padilla Miranda
Jeff Irvin
Maria del Mar Zamora Gomez
James Van Kollenburg
Haley Ehrlich

Felix Del Prado
Alberto Alba Alonso
Antonio Serrano Pinto
Henry Leon
Daniel Matamala
Diego Acevedo
Gonzalo Mazuela Aguila
Henry Leon Higuera
Javier Ruiz
Johan Rodrigo Lopez Torres
Jose Antonio Sanchez Canovas
Jose David Lorca
Jose Leonardo Mujica Quintero
Leonardo Orduz Rincon
Levi Marun
Liang Mateos
Michael Manganiello
Paul Causey
Rosalbina Pinzon

cc: Stephen Hoge, MD
Diane Montross
Moncef Slaoui, PhD,
Anthony Fauci, MD
Carl Dieffenbach, PhD
John Mascola, MD
Julie Ledgerwood, DO
Peter Marks, MD, PhD
Celia Witten, MD, PhD
Lawrence Corey, MD
Nancy Pelosi
Congressional Black Caucus