SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement and Release is entered into by and among the Center for Science in the Public Interest, EpicGenetics, Inc., the Gillis Controlled Companies (defined below as EpicGenetics, Inc., Bruce S. Gillis M.D., M.P.H., Inc., Center for Immunology Science LLC, and Immunology Diagnostics, LLC), and Bruce Gillis, MD.

RECITALS

WHEREAS, on October 4, 2023, the Center for Science in the Public Interest filed an Action (defined below) in the District of Columbia Superior Court, styled *Center for Sci. in the Pub. Interest v. EpicGenetics, Inc.* (Case No. 2023-CAB-006126), the Complaint (defined below) alleged a cause of action under the D.C. Consumer Protection and Procedures Act, and in support of that cause of action, alleged that EpicGenetics, Inc. made certain false or misleading statements to consumers in the District of Columbia about the efficacy of the FM/a (defined below) and 100Sure (defined below) laboratory-developed tests, and the ability of individuals who tested positive for fibromyalgia or a condition it referred to as "immune deficiency disease" to participate in experimental treatment trials testing treatments for such conditions.

WHEREAS, on February 15, 2024, EpicGenetics, Inc. answered the Complaint, denying the material allegations and raising certain affirmative defenses. EpicGenetics, Inc. denies the material allegations in the Complaint, has denied and continues to deny any wrongdoing and any liability to CSPI in any amount in connection with the claims asserted in the Action, and contends that it would prevail in the Action.

WHEREAS, CSPI believes that the allegations in the Complaint are strong as a matter of fact and law and that it would prevail in the Action.

WHEREAS, out of a desire by the parties to avoid the expense, disruption, and inconvenience of litigation, the parties to this Settlement Agreement and Release have agreed to this Agreement.

NOW, THEREFORE, intending to be legally bound, in consideration of the mutual covenants and promises herein contained, the parties to this Settlement Agreement and Release have agreed to the following terms and conditions:

Agreement

1. **DEFINITIONS.** As used in this Settlement Agreement and Release, the following terms have the following meanings, unless this Agreement specifically provides otherwise:

    a. The term "Action" refers to the Complaint filed in *Center for Sci. in the Pub. Interest v. EpicGenetics, Inc.* (Case No. 2023-CAB-006126 D.C. Super. Ct.), alleging that EpicGenetics, Inc. made certain false or misleading statements about the efficacy of certain laboratory-developed tests and the ability of individuals who tested positive for fibromyalgia or a condition it referred to as "immune deficiency disease" to participate in experimental treatment trials testing treatments for such conditions, and EpicGenetics, Inc.'s Answer, including affirmative defenses.

b. The terms "Advertise," "Advertised," "Advertisement," "Advertising," "Advertising materials," "Market," "Marketed," "Marketing," and "Marketing Materials" refer to the use by the Gillis Controlled Companies (defined below) or any third party on their behalf, of any commercial consumer-directed or physician/healthcare provider-directed material, including, but not limited to, any print advertisement, internet advertisement, radio advertisement, television advertisement, billboard, banner advertisement, website, blog post, letter, postcard, brochure, pamphlet, packaging, offer, placard, in-store display or other attempt, effort, or process that conveys any information, invitation or offer to any consumer to purchase or otherwise acquire in a commercial context, and/or any physician to prescribe or order in a commercial context, the Relevant Diagnostic Test(s) (defined below), IMBXX (defined below), or to participate in a Relevant Treatment Trial(s)(defined below) in connection with the Marketing or Advertising of a Relevant Diagnostic Test or IMBXX. These terms do not include, clinical research activities, the publication of peer-reviewed scientific papers, presentations at medical conferences, or other non-marketing and non-consumer focused speech.

c. The term "Agreement" refers to this Settlement Agreement and Release.

d. The term "BSURE Test" refers to the Laboratory-Developed Test (defined below) for the medical condition Fibromyalgia and/or a condition the Gillis Controlled Companies (defined below) call "immune deficiency disease(s)" (defined below), which test is offered by the Gillis Controlled Companies to diagnose Fibromyalgia and/or "immune deficiency disease(s)," including if offered under a different name. For the avoidance of doubt, the term "BSURE Test" only refers to the test when offered by the Gillis Controlled Companies and does not otherwise apply to the test or its underlying science.

e. The terms "Center for Science in the Public Interest" and "CSPI" refer to the Center for Science in the Public Interest, a public-interest organization organized and existing under the laws of the District of Columbia, with a principal place of business in Washington, D.C., and its present and future officers, directors, employees, parents, distributors, principals, agents, successors, trustees, attorneys, representatives, executors, and assigns of all of the foregoing persons and entities.

f. The term "CSPI Released Parties" refers to those persons and entities receiving a release in Section 13(b) of the Agreement, and are CSPI, its present and future officers, directors, employees, distributors, principals, agents, attorneys, representatives, and assigns of all of the foregoing persons and entities.

g. The term "CSPI Releasing Parties" refers to those persons and entities giving a release in Section 13(a) of the Agreement, and are CSPI, its present and future officers, directors, employees, distributors, principals, agents, attorneys, representatives, and assigns of all of the foregoing persons and entities.

h. The term "Complaint" refers to the Complaint filed in the Action.

i. The term "DNA" refers to deoxyribonucleic acid. It is defined by the National Institutes of Health's National Human Genome Research Institute as "the molecule that carries genetic information for the development and functioning of an organism. DNA is made of two linked strands that wind around each other to resemble a twisted ladder -- a shape known as a double helix." https://www.genome.gov/genetics-glossary/Deoxyribonucleic-Acid.

j. The term "Effective Date" refers to the date on which this Agreement is effective, and shall be the last date on which this Agreement is executed by all Parties and their counsel on their behalf.

k. The terms "EpicGenetics, Inc." and "EpicGenetics" refer to EpicGenetics, Inc., a corporation that at the time the Action was filed, was organized and existed under the laws of Delaware and had a principal place of business in California, and its present and future officers, directors, employees, parents, distributors, principals, agents, successors, trustees, attorneys, representatives, executors, and assigns of all of the foregoing persons and entities.

l. The terms "Federal Food, Drug, and Cosmetic Act" and "FDCA" refer to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

m. The term "FDA" refers to the U.S. Food and Drug Administration.

n. The term "FM" refers to the medical condition Fibromyalgia.

o. The term "FM/a Test" refers to the laboratory-developed test that was Marketed by EpicGenetics to diagnose FM as alleged in the Complaint.

p. The term "Former RDTs" collectively refers to the FM/a Test and the 100Sure Test (defined below).

q. The term "Dr. Gillis" refers to Bruce Gillis, MD, the founder and Chief Executive Officer of EpicGenetics and the Gillis Controlled Companies (defined below).

r. The terms "Gillis Controlled Companies" and "GCCs" refer to companies owned, controlled, and/or operated by Dr. Gillis to the extent that those companies Market a Relevant Diagnostic Test (defined below), IMBXX (defined below), or a Relevant Treatment Trial (defined below) within the United States. GCCs covered by this Agreement are EpicGenetics, Bruce S. Gillis M.D., M.P.H., Inc., a California corporation with a principal place of business in California, Center for Immunology Science LLC, a New Mexico limited liability corporation with a principal place of business in California, and Immunology Diagnostics, LLC, a New Mexico limited liability corporation with a principal place of business in California, and their present and future officers, directors, employees, parents, distributors, principals, agents, successors, trustees, attorneys, representatives, executors, and assigns of all of the foregoing persons and entities.

s. The term "GCCs Released Parties" refers to those persons and entities receiving a release in Section 13(a) of the Agreement, and are EpicGenetics, Dr. Gillis, the GCCs, and their present and future officers, directors, employees, distributors, principals, agents, attorneys, representatives, and assigns of all of the foregoing persons and entities. Notwithstanding anything to the contrary in the Agreement, Bruce S. Gillis M.D., M.P.H., Inc. is only a party to this Agreement and a GCCs Released Party for purposes of Section 13(a) solely concerning its activities related to the FM/a Test, and any release given to Bruce S. Gillis, M.D., M.P.H., Inc. is limited to the FM/a Test.

t. The term "GCCs Releasing Parties" refers to those persons and entities giving a release in Section 13(b) of the Agreement, and are EpicGenetics, Dr. Gillis, the GCCs, and their present future officers, directors, employees, distributors, principals, agents, attorneys, representatives, and assigns of all of the foregoing persons and entities. Notwithstanding anything to the contrary in the Agreement, Bruce S. Gillis M.D., M.P.H., Inc. is only a party to this Agreement and a GCCs Releasing Party for purposes of Section 13(b) solely concerning its activities related to the FM/a Test.

u. The term "IMBXX" refers to the compound currently offered in the United States as a dietary supplement with 250 mg of the ingredient *M. smegmatis* and any similar product Marketed to consumers as a dietary supplement by the GCCs in the United States under a different name that makes IMBXX Claims (defined below).

v. The term "IMBXX Claims" refers to the immunity support claims currently made on https://imbxx.com/ and other substantively similar claims made by the GCCs regarding IMBXX. Screenshots of such claims are attached hereto as Exhibit A.

w. The terms "Immune Deficiency Disease(s)" and "IDD" refer to "Immune Deficiency Disease(s)," which as alleged in the Complaint, were terms used by the GCCs.

x. The terms "Laboratory-Developed Test(s)" and "LDT(s)" refer to laboratory-developed test(s), which are described in the Complaint as "a type of in vitro clinical test that are developed and used in a single laboratory" that have historically not been "require[d] to go through pre-market review or comply with other applicable FDCA requirements" due the exercise of enforcement discretion by the FDA.

y. The terms "New Dietary Ingredient Notice" and "NDIN" refer to the New Dietary Ingredient Notice process contained in the FDCA, 21 U.S.C. § 350b(a)(1).

z. The term "Parties" refers to the Parties to this Agreement, which are CSPI, EpicGenetics, GCCs, and Dr. Gillis, each of whom is referred to individually as a "Party" and collectively with the others as the "Parties."

aa. The terms "Relevant Diagnostic Test(s)" and "RDT(s)" refer to the Former RDTs, the BSURE Test, and similar blood tests Advertised by the GCCs to consumers and

physicians making similar claims. For the avoidance of doubt, the terms "Relevant Diagnostic Test(s) and RDTs" only refers to the test when offered by the Gillis Controlled Companies and does not otherwise apply to the tests or their underlying science. Excluded from the definition of Relevant Diagnostic Tests is any future DNA-based test (*i.e.*, a diagnostic test that identifies mutations in a patient's genes, chromosomes, or proteins) developed by the GCCs, or any test that is not offered for sale to consumers and/or to physicians to prescribe or order in a commercial transaction.

bb. The term "Relevant Treatment Trial(s)" refers to any future human research study Marketed by the GCCs or any third party on the GCCs' behalf studying the safety and/or efficacy of IMBXX or a treatment for FM or IDD as alleged in the Complaint.

cc. The term "100Sure Test" refers to the test for FM and/or IDD that was Marketed by EpicGenetics to diagnose FM and/or IDD as alleged in the Complaint. The GCCs Released Parties represent that the 100Sure Test was never sold to any patient in the District of Columbia or elsewhere.

2. **No Admission of Wrongdoing:** EpicGenetics and the GCCs deny any wrongdoing or liability to CSPI. This Agreement was entered into based on a mutual desire to avoid the uncertainties of, risk and delays associated with discovery, motions practice, a trial and any subsequent appeals, and the general resources required in protracted litigation. No Party to this Agreement is permitted to make any public statement concerning whether the GCCs have denied any wrongdoing or liability to CSPI that is inconsistent with this Agreement.

3. **Follow-Up Communication:** Within two weeks of the Effective Date of this Agreement, the GCCs will send the negotiated follow-up communication, in the form attached hereto as Exhibit B, to the five patients and one doctor who ordered a RDT sent to the District of Columbia.

4. **Discontinuance of the Former RDTs:** The GCCs Released Parties represent that EpicGenetics has ceased Advertising, Marketing, or selling the Former RDTs to consumers and/or encouraging physicians to prescribe or order them for consumers. As part of this Agreement, and in exchange for the Releases contained herein, the GCCs Released Parties agree that they will not in the future Advertise, Market, or sell the Former RDTs to consumers and/or Advertise, Market, or sell the Former RDTs to physicians to prescribe or order for consumers.

5. **Competent and Reliable Scientific Evidence Standard:** The competent and reliable scientific evidence standard is the catch-all substantiation standard under this Agreement for claims about the health, safety, and benefits of RDTs and IMBXX. The GCCs Released Parties agree that, unless otherwise specified in this Agreement, when this Agreement requires substantiation for a health, safety, and/or benefits Marketing claim, the Parties intend for substantiation to mean competent and reliable scientific evidence as that phrase is used by the Federal Trade Commission and FDA. *See* Federal Trade Commission, Health Products Compliance Guidance (2022), https://bit.ly/3JRbPVD;

FDA, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (2009), https://bit.ly/2ZewbiC. The GCCs Released Parties further agree that this standard generally requires health-related claims to be substantiated by a randomized controlled study.

6. **Use of "Definitive," "Know the Truth Once and for All," and Similar Claims:** The GCCs agree that they will not use the terms "definitive," "know the truth once and for all," and similar terms in making claims in the Marketing, Advertising, and sale of the RDTs for five (5) years from the Effective Date of this Agreement unless they provide notice to CSPI of a controlled study, which had been performed on the RDTs, establishing the Tests have a diagnostic accuracy of equal to or greater than 95%, in which case after giving notice, these terms could be used. CSPI agrees that the GCCs may refer to the RDTs as "accurate," providing proof," or providing "real answers," and similar terms for the diagnosis of fibromyalgia and may call their RDT "BSURE." CSPI agrees that the term "accurate" and similar terms applies to the assay technology used in the BSURE Test.

7. **IDD:** The Parties agree to the following concerning claims about Immune Deficiency Diseases.

   a. The RDTs will not be Advertised, Marketed, or sold for purposes of diagnosing IDD, or any immune deficiency diseases or immune deficiency disorders other than FM, until such time as there is competent and reliable scientific evidence to support any such Advertising, Marketing, or sale.

   b. The GCCs may claim that the RDTs diagnose FM, that FM is an immune deficiency disease associated with a deficiency in the immune system, that FM results in certain symptoms, such as chronic fatigue and pain, and that people with such symptoms may be a good candidate for the RDTs.

8. **DNA Claims:** The Parties agree that the RDTs are not DNA tests. The Parties further agree to the following.

   a. Except as provided in Section 8(b) of this Agreement, for five (5) years from the Effective Date of this Agreement, the GCCs agree not to Advertise, Market, or sell the RDTs as a "DNA" test, state or imply that the RDTs use DNA science as part of the RDT blood test technology or RDT analysis for a patient. The GCCs will not make any claim comparing the accuracy of the RDTs to DNA-based tests. For example, this provision would prohibit the GCCs from making statements, such as, "this test uses DNA precision to identify immune system deficiencies;" "the accuracy of the BSURE Blood Test is based on DNA-based research"; "Rely on DNA evidence"; "the science that is associated with this blood test is DNA-based. Yes-DNA!"

   b. The GCCs may claim that there is a connection between FM and DNA abnormalities, if supported by competent and reliable scientific evidence (as defined by Section 5 of this Agreement). For example, the GCCs may accurately describe the findings of the

study conducted by Dr. Gillis or link to it. *See Gayatry Mohapatra, Identification of unique genomic signatures in patients with fibromyalgia and chronic pain,* Nature: Scientific Reports (2024). The GCCs may also claim, for example, that "In a clinical study to identify DNA characteristics of FM patients that resulted in a peer-reviewed paper, '*Identification of unique genomic signatures in patients with fibromyalgia and chronic pain*,' patients who tested positive for FM using the RDTs were shown to have unique DNA characteristics."

c. The BSURE Test, which is a blood test, is not a DNA-based test.

d. The GCCs may not make any DNA claims about IMBXX and any similar product Marketed to consumers as a dietary supplement by the GCCs in the United States under a different name that makes IMBXX Claims, which claims are not supported by competent and reliable scientific evidence.

e. The GCCs may make the following DNA claims in connection with the Marketing, Advertising, and sale of IMBXX (and any similar product Marketed to consumers as a dietary supplement by the GCCs in the United States under a different name that makes IMBXX Claims), including, but not limited to, on the IMBXX bottle, packaging, and any inserts; Marketing materials; and the website https://imbxx.com/: "DNA=THE SCIENTIFIC GOLD STANDARD"; "IMMUNE SYSTEM/MICROBIOME DNA VERIFIED®"; and "DNA-Based Science"

9. **Relevant Treatment Trials:** The GCCs deny that they have made any false or misleading statements regarding any clinical studies or trials and represent that a clinical study regarding IMBXX was completed prior to the initiation of the Action. The Parties agree to the following concerning claims or statements about Relevant Treatment Trials in the future.

a. The GCCs may not make any false or misleading statements or claims regarding Relevant Treatment Trials, and agree that they will not claim a Relevant Treatment Trial is available or expected to be available when it is not.

b. The GCCs are prohibited from making any claims suggesting that patients and consumers can enroll in any Relevant Treatment Trials unless such a trial has been designed and it is reasonably likely to occur in the near future. Claims about Relevant Treatment Trials must be removed reasonably promptly after enrollment for the trial has ended or the trial has been canceled, whichever is sooner.

c. Claims about Relevant Treatment Trials must provide the trial's location and accurately describe the treatment trial in sufficient detail to provide doctors, patients, and consumers with a reasonable understanding of a person's eligibility to participate and the design of the trial.

d. The GCCs may not make any claims, either explicitly or implicitly, that substances being tested in the Relevant Treatment Trials are safe or effective for the purposes under investigation.

10. **IMBXX:** Concerning the Advertising, Marketing, and/or sale of IMBXX, the Parties agree to the following.

    a. The following is prohibited concerning the Advertising, Marketing, and/or sale of IMBXX:

        i. False, misleading and unsubstantiated claims are prohibited;

        ii. The GCCs will not Market IMBXX on their websites that Market the RDTs in any manner that states or implies that IMBXX is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease;

        iii. The GCCs will not target the Marketing of IMBXX to consumers who ordered the RDTs, *i.e*., there will be no Marketing emails, mailings, telephone calls, or other Marketing based on information provided by consumers or physicians who ordered the RDTs in an attempt to get patients to purchase or physicians to recommend IMBXX, which Marketing states or implies that IMBXX is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; and

        iv. The GCCs will employ filters on any GCCs' controlled website Marketing IMBXX in order to prevent disease-related claims from being made in comments. Such filters will remove the term fibromyalgia and similar terms or phrases and the GCCs will reasonably monitor such websites to remove such claims.

    b. Before entering into this Agreement, the Parties agreed that the GCCs would retain Vanguard Global as a consultant to determine whether *M. smegmatis* bacteria is a new dietary ingredient for which a NDIN is required under the FDCA, and that the Parties would abide by Vanguard Global's conclusion on this issue, which conclusion is stated in a report containing an explanation of the basis for the conclusion, and which report is provided to CSPI on or before May 30, 2024. Because Vanguard Global's Report concluded that *M. smegmatis* bacteria is not a new dietary ingredient for which an NDIN is required under the FDCA, the GCCs will not submit an NDIN to FDA.

11. **Fees and Costs**: Except as provided in Section 12, concerning a payment toward CSPI's attorneys' fees, each Party shall bear its own costs, expenses, and attorneys' fees incurred in the Action, including arising out of the negotiation, execution, delivery, and performance of this Agreement, and waive any right to collect them from the opposing Party.

12. **Payment Toward CSPI's Attorneys' Fees:** The following provisions shall govern the payment by the GCCs of some of CSPI's attorneys' fees.

    a. On or before July 31, 2024, the GCCs shall pay to CSPI's attorneys the total sum of $158,000.00.

b. The payment of $158,000.00 to CSPI's attorneys shall be made by wire to Reese LLP via the following account and wire instructions:

Name of Account: Reese LLP
Bank Name and Address: JP Morgan Chase Bank, N.A.
2540 Broadway
New York, New York 10025

ABA Routing No.: 021000021
Operating Account No.: 533153315

13. Release:

a. In consideration of the payment set forth in Section 12 and the other relief provided in this Agreement, the CSPI Releasing Parties release the GCCs Released Parties as of the Effective Date of this Agreement, from any and all claims, demands, rights, damages, obligations, suits, debts, liens, and causes of action under common or statutory law (federal, state, or local) of every nature and description whatsoever, ascertained or unascertained, suspected or unsuspected, existing or claimed to exist, including unknown claims by the CSPI Releasing Parties that were asserted or could have been asserted in the Action; and all claims, demands, rights, damages, obligations, suits, debts, liens, and causes of action under common or statutory law (federal, state, or local) of every nature and description whatsoever, ascertained or unascertained, suspected or unsuspected, existing or claimed to exist, including unknown claims by the CSPI Releasing Parties against the GCCs Released Parties relating to the RDTs, IMBXX, and Relevant Treatment Trials as of the Effective Date of this Agreement.

b. The GCCs Releasing Parties hereby release the CSPI Released Parties from any and all claims, demands, rights, damages, obligations, suits, debts, liens, and causes of action under common or statutory law (federal, state, or local) of every nature and description whatsoever, ascertained or unascertained, suspected or unsuspected, existing or claimed to exist, including, but not limited to, unknown claims regarding or relating to the Action and any pre-suit notice relating to the Action.

14. Stipulation of Dismissal: Provided the payment set forth in Section 12 is received by July 31, 2024, CSPI shall file by August 9, 2024, the Stipulation of Dismissal with Prejudice pursuant to Rule 41(a)(1)(A)(ii), in a form attached hereto as Exhibit C.

15. Pre-Suit Dispute Resolution Mechanism: Before filing any lawsuit based on this Agreement, the Parties agree to comply with the following pre-suit dispute resolution mechanism.

a. CSPI shall provide written notice by email of what it alleges is a breach of this Agreement (that is, an action or inaction by the GCCs that CSPI contends is inconsistent with the commitments in this Agreement) and that it seeks to enforce such provision of this Agreement.

b. The GCCs shall have fourteen (14) days from receipt of CSPI's email to respond in writing by email.

c. If the GCCs contend that they have not so breached a commitment, but CSPI continues to believe that there has been a breach of this Agreement or continues to seek to enforce such provision of this Agreement, CSPI shall have fourteen (14) days from receipt of the GCCs' email to reply in writing by email.

d. If after seven (7) days from the GCCs' receipt of CSPI's reply email, the Parties have not been able to resolve the issue between themselves, before a lawsuit is filed, a settlement call and/or meeting must be held involving the principals of the Parties in an effort to engage in a good faith attempt to resolve the issue in dispute.

e. The parties do not waive any rights by agreeing to this process.

16. Choice of Law and Venue: The law of the District of Columbia, without reference to conflict of law provisions, shall govern any disputes under this Agreement. Provided the provisions of Section 15 (entitled "Pre-Suit Dispute Resolution Mechanism") have been complied with, the Parties agree that disputes about this Agreement shall be filed at the District of Columbia Superior Court. However, the GCCs preserve their right, in District of Columbia Superior Court, to challenge an action to enforce this Agreement by asserting arguments based on lack of personal jurisdiction, venue, or inconvenient forum depending on the nature of the alleged breach of this Agreement. The GCCs agree to waive any right to seek removal of such a case to federal court.

17. Notice:

a. Notice to Be Given to CSPI:

For notice to be given or documents sent to CSPI, such notice or documents shall be sent by overnight courier, with a copy sent by email, addressed to:

CSPI
1250 I Street, N.W.
Suite 500
Washington, DC 20005
Attention: Senior Litigation Director
Lisa S. Mankofsky
Email: Lmankofsky@cspinet.org

b. Notice to Be Given to the GCCs and/or Dr. Gillis:

For notice to be given or documents sent to the GCCs and/or Dr. Gillis, such notice or documents shall be sent by overnight courier, with a copy sent by email, addressed to:

Dr. Bruce Gillis
c/o Hyman, Phelps & McNamara PC
700 13th St. NW
Suite 1200
Washington, DC 20005
Attention: J.P. Ellison
Email: jellison@hpm.com

c. Change in Contact Information

The Parties may update their contact information by providing notice to the other by email so as long as the Party changing its contact information requests confirmation of receipt of such email and such confirmation is received.

18. Miscellaneous:

a. Entire Agreement: This Agreement constitutes an integrated contract and the entire understanding of the Parties and supersedes all prior and/or contemporaneous understandings, oral, written, or otherwise, related to the subject matter of this Agreement that conflict with this Agreement. This Agreement shall not be modified in any respect except by a writing executed by the signatories of this Agreement.

b. **Authority**: Each person who executes this Agreement on behalf of any Party to this Agreement represents and warrants that they have been authorized by such Party to enter into this Agreement and to bind the Party.

c. Benefit and Burden: This Agreement shall be binding upon, and inure to the benefit of, the Parties and their respective present and future officers, directors, shareholders, employees, predecessors, affiliates, subsidiaries, distributors, principals, insurers, administrators, agents, attorneys, representatives, experts, consultants, and assigns of all of the foregoing persons and entities. This Agreement shall be binding, enforceable, discoverable, and admissible to establish the rights, obligations, and duties of the Parties hereunder in any action brought to enforce this Agreement.

d. **Severability**: If any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable, or void, such provision shall be ineffective only to the extent of such illegality or unenforceability. The remainder of this Agreement shall remain in full force and effect, and the parties shall amend or otherwise modify this Agreement to replace the affected provision or portion thereof with an effective and valid provision that gives effect to the intent of the parties to the maximum extent possible.

e. **Jointly Drafted**: This Agreement shall be deemed to have been drafted jointly by the Parties. No law or rule requiring the interpretation of uncertainties against a drafting party shall apply.

f. **Interpretation of Defined Terms**: The plural of any defined term includes the singular, and the singular of any defined term includes the plural, as the case may be.

g. **Parties Represented by Counsel of Their Choice**: The Parties acknowledge that they have been represented in the negotiations for, and in preparation of, this Agreement by counsel of their choice, that they have read this Agreement and have had it fully explained to them by such counsel, and that they are fully aware of the contents of this Agreement and of the legal effect of each and every provision thereof. The Parties understand, acknowledge and, agree that each Party to this Agreement has performed an independent investigation of the facts and law surrounding this matter and all underlying issues relating thereto, which each Party deems necessary.

h. **Execution in Counterparts and with Electronic Signatures**: This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which taken together shall be deemed to be one and the same instrument. Delivery of an executed counterpart by PDF or other electronic delivery shall be equally effective as delivery of a manually executed counterpart. This Agreement may be executed using electronic signatures.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the dates set forth below.

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

By: _____ Dated: July 29, 2024
Peter G. Lurie, M.D., M.P.H.
President and Executive Director

ATTORNEYS FOR CENTER FOR SCIENCE IN THE PUBLIC INTEREST

CENTER FOR SCIENCE IN THE PUBLIC INTEREST LITIGATION DEPARTMENT

By: _____ Dated: July 29, 2024
Lisa S. Mankofsky, Esq.

REESE LLP

By: _____ Dated: July ___, 2024
Michael R. Reese, Esq.

g. **Parties Represented by Counsel of Their Choice**: The Parties acknowledge that they have been represented in the negotiations for, and in preparation of, this Agreement by counsel of their choice, that they have read this Agreement and have had it fully explained to them by such counsel, and that they are fully aware of the contents of this Agreement and of the legal effect of each and every provision thereof. The Parties understand, acknowledge and, agree that each Party to this Agreement has performed an independent investigation of the facts and law surrounding this matter and all underlying issues relating thereto, which each Party deems necessary.

h. **Execution in Counterparts and with Electronic Signatures**: This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which taken together shall be deemed to be one and the same instrument. Delivery of an executed counterpart by PDF or other electronic delivery shall be equally effective as delivery of a manually executed counterpart. This Agreement may be executed using electronic signatures.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the dates set forth below.

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

By: _____ Dated: July ___, 2024
Peter G. Lurie, M.D., M.P.H.
President and Executive Director

ATTORNEYS FOR CENTER FOR SCIENCE IN THE PUBLIC INTEREST

CENTER FOR SCIENCE IN THE PUBLIC INTEREST LITIGATION DEPARTMENT

By: _____ Dated: July ___, 2024
Lisa S. Mankofsky, Esq.

REESE LLP

By: _____ Dated: July 29, 2024
Michael R. Reese, Esq.

GILLIS CONTROLLED COMPANIES (which are EPICGENETICS, INC., BRUCE S. GILLIS, M.D., M.P.H., INC., CENTER FOR IMMUNOLOGY SCIENCE, LLC, and IMMUNOLOGY DIAGNOSTICS, LLC)

By:_____ Dated: July 30, 2024
Bruce Gillis, MD
Founder and Chief Executive Officer

BRUCE GILLIS, MD

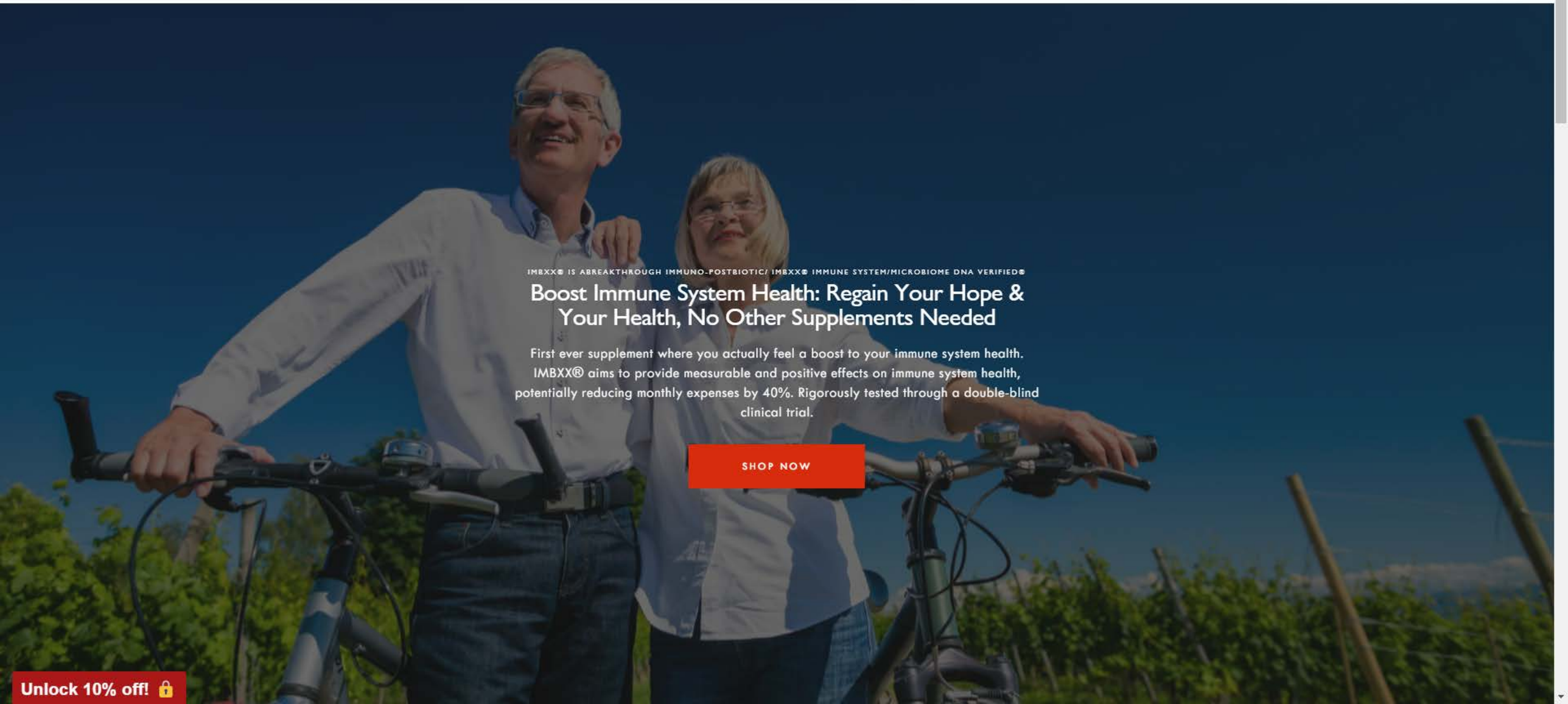
By:_____ Dated: July 30, 2024
Bruce Gillis, MD

ATTORNEYS FOR GILLIS CONTROLLED COMPANIES AND BRUCE GILLIS, MD

HYMAN, PHELPS & MCNAMARA P.C.

By: J.P. Ellison Dated: July 30, 2024
James P. Ellison, Esq.

EXHIBIT A



IMBXX® IS ABREAKTHROUGH IMMUNO-POSTBIOTIC/ IMBXX® IMMUNE SYSTEM/MICROBIOME DNA VERIFIED®

Boost Immune System Health: Regain Your Hope & Your Health, No Other Supplements Needed

First ever supplement where you actually feel a boost to your immune system health. IMBXX® aims to provide measurable and positive effects on immune system health, potentially reducing monthly expenses by 40%. Rigorously tested through a double-blind clinical trial.

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How to take IMBXX®?

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Developed with the expertise of faculty and staff from the University of Illinois College of Pharmacy.

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Other Ingredients: Methylcellulose, vegetable stearate, silicon dioxide
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Research Article

Immune-Modulating Effects of Mycobacteria

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ABSTRACT

Several species of *Mycobacterium* have been identified as having the ability to modulate immune responses, even as heat-killed preparations. Our goal was to identify mycobacteria that could potentially act in a safe and non- toxic immune-modulating effect by promoting the production of specific chemokine and cytokine responses with a potential application for impacting the microbiome. We relied on the following *Mycobacterium* strains: *M. smegmatis*, *M. agri*, *M. phlei*, *M. tokaiense*, *M. brumae*, *M. aurum*, and *M. obuense*. *M. smegmatis* and *M. agri* were the most effective in inducing immune responses in cultured Peripheral Blood Mononuclear Cells (PBMC) manifested by extracellular productions of the cytokine IL-6, as well as the chemokines IL-8, MIP-1α and MIP-1β. Correlation analyses and immune challenges to the bacterial mixtures showed that while cytokine and chemokine responses to *M. smegmatis* and *M. agri* were similar, they were distinct from responses to either *B. subtilis* or Phyto-Hemagglutinin (PHA) suggesting that *Mycobacterium* strains and *B. subtilis* have different effects on the immune system. Our methodology for comparing immune responses of bacterial preparations may provide a useful tool for studying immune effects of pathogenic and non-pathogenic bacteria. Distinct immune-modulatory properties of multiple species may have potential implications for immunotherapy of cancer as well as treatments of various immune-deficiency disorders.

Keywords: Mycobacteria; Cytokines; Chemokines; Immune responses; Peripheral blood mononuclear cells; *B. subtilis*; Immunotherapy

INTRODUCTION

Mycobacteria have diverse and established significant roles in modulating immune system responses [1-3]. This includes the recognition of the impact of the Bacillus-Calmette-Guerin (BCG) vaccine which is derived from M. bovis [4]. Applications of these bacteria have been utilized for immunotherapy in the treatment of multiple types of cancer [5], as well as having molecular effects on intestinal and extra-intestinal organs, and in reference to microbiome interactions and immune-mediated diseases [6].

A number of studies have also shown that the mycobacterial cell wall can stimulate the immune system [1] and it has also been documented in killing cancer cells [7-8]. Other mycobacterial preparations were shown to induce immune responses in cultured cells [3,9-14], as well as have been used to evaluate immune-stimulation activities of various *Mycobacterium* strains [2]. Interestingly, *Mycobacterium* has been especially detailed in relation to the use of *M. bovis* as a consequence of the utilization of the BCG vaccine [15]. Because of the documented potential side effects of BCG vaccine, we sought other species of Mycobacterium that could effectively induce immune-modulating effects on peripheral blood mononuclear cells whose responsibility is to produce vital chemokines and cytokines. These were the Myobacterium strains of *M. smegmatis*, *M. agri*, *M. phlei*, *M. tokaiense*, *M. brumae*, *M. aurum*, and *M. obuense*. For comparative purposes, we also did parallel peripheral blood mononuclear cell challenges with *B. subtilis* and PHA.

MATERIALS AND METHODS

Bacterial cells

M. smegmatis isolates were provided by the Institute for Tuberculosis Research, College of Medicine at the University of Illinois at Chicago. Other *Mycobacterium* strains were acquired from the American Tissue Culture Collection, including *M. agri*, ATCC27406; *M. phlei*, ATCC11758; *M. tokaiense*, ATCC27282; *M. smegmatis*, ATCC19420; *M. brumae*, ATCC51384; *M. aurum*, ATCC23366; *M. obuense*, ATCC27023; as well as *B. subtilis*, ATCC6051. Mycobacteria were grown in a medium containing 5 g/L L-asparagine, 5 g/L Potassium dihydrogen phosphate, 1.5 g/L Citric acid, 0.5 g/L Magnesium sulfate, 20 ml/L Glycerol, 0.2 % v/v Tween 80. The pH was adjusted to 7.4 and the medium was filter sterilized. Each strain was inoculated separately into 15 ml

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of the medium in 50 ml bio-reaction tubes and incubated at 37°C skin, abdomen, and an abscess were characterized, grown and with shaking (220 rpm) for 3 days. A medium without inoculum maintained at the Institute for Tuberculosis Research, College of was also incubated along with the mycobacteria as a blank control. Medicine at the University of Illinois at Chicago. To determine After 3 days, cells were collected by centrifugation at 9000 rpm and immune responses to these isolates, we isolated PBMC from healthy washed three times with borate-buffered saline, pH 8.0, weighed individuals, cultured the cells in the presence of either 50 µg/ml, (wet weight), and resuspended in the same buffer at 100 mg/ml The 100 µg/ml or 200 µg/ml of heat-killed bacteria and measured cells were heat-killed by autoclaving at 121°C for 20 minutes. The concentrations of the cytokine IL-6 as well as the chemokines IL-8, samples were also submitted for mass spectrometry analysis and the MIP-1α and MIP-1β in tissue culture supernatants. As shown in results showed no media residue in the samples (not shown). The Figures 1A-1D, all three isolates stimulated secretions of these four dry-freezed *B. subtilis* samples were prepared by washing bacterial proteins showing a significant increase in cytokine and chemokine pellets with borate-buffered saline, pH 8.0 three times, weighed levels in stimulated PBMC cultures compared to controls. Protein and suspended in phosphate-buffered saline, pH 7.4 at 100 mg/ml levels did not increase at higher mycobacterial cell concentrations (wet weight). The samples were then autoclaved as described above.suggesting that the immune responses were close to the saturation levels.

PBMC challenges To determine if all three isolates had the same effect on the

immune cells we performed a correlation analysis of extracellular

PBMC were isolated from blood collected from healthy individuals productions of different cytokines and chemokines

in these

by density gradient centrifugation as described earlier [17]. challenges. The Pearson correlation test for different

challenges was

Cells were cultured at 106 cells/ml in RPMI 1640 medium performed by using normalized concentrations of four

proteins to

supplemented with 0.5% penicillin-streptomycin solution (10,000 correct for large differences in concentrations of

different cytokines

U/ml penicillin, 10,000 µg/ml streptomycin) 0.5% L-glutamine and chemokines (Figure 1A). As shown in Table 1,

secretions

and 5% fetal bovine serum. One ml PBMC cultures were placed in of all cytokines and chemokines correlated well for

all three *M.*

24-well tissue culture dishes followed by the addition of heat-killed *smegmatis* challenges suggesting that all three

Protein assays

isolates evoked the

After the overnight culture of PBMC, 0.5 ml medium was

different patterns of

removed from each plate, centrifuged at 16,000g at +4°C

for 2 minutes and clear cell free liquid was placed in a

minus 70°C freezer. Cytokine and chemokine

concentrations in PBMC tissue culture supernatants were

measured by using multiplex immunoassay using

Luminex xMAP technology. Four beads array technology

(17). The

human cytokine IL-6, as well as the chemokines IL-8, MIP-

for determining the basal levels of the extracellular production of

Statistical methods

We compared cytokine and chemokine responses in

challenge compared to

immune challenges by using the Z-test. The confidence

level in all tests was set at 5%. Correlations between

productions of different cytokines and chemokines in

immune challenges were evaluated by using the Pearson correlation test. For this test we used normalized cytokine and chemokine concentration values to account for large differences in levels of different proteins. Each protein concentration was normalized to a mean concentration value of corresponding proteins across all analyzed challenges. A correlation of cytokine and chemokine productions in two challenges was considered strong when their r value was larger than 0.7. All statistical analyses were performed in Microsoft Excel.

RESULTS

M. smegmatis stimulated extracellular productions of cytokines and chemokines in PBMC cultures

Three isolates of *M. smegmatis* strains collected from feline

M.smegmatis and *M. agri* challenges: Induced similar patterns of cytokine and chemokine expressions

To compare cellular immune responses to *M. smegmatis* with responses to other *Mycobacterium* strains, we challenged PBMC to either 50 µg/ml or 100 µg/ml mycobacterial preparations from the following strains: *M. agri*, *M. phlei*, *M. tokaiense*, *M. brumae*, *M. aurum*, and *M. obuense*. *M. smegmatis* type strain was used as a reference. As shown in Figures 2A-2D, apart from *M. smegmatis*, *M. agri* induced high immune responses in mononuclear cells manifested by significant extracellular cytokine and chemokine productions. The concentrations of IL-6, IL-8, MIP-1α and MIP-1β were higher at 100 µg/ml of these *Mycobacterium* strains *vs.* lower doses. Some increases in cytokine and chemokine levels were also observed in response to 50 µg/ml *M. brumae*. However, concentrations of these proteins decreased at 100 µg/ml *M. brumae*. Also, very weak responses were observed in the *M. obuense* challenges. We also observed significant subject-to-subject variations in cytokine and chemokine responses (compare Figure 2A to Figure 1A). The Pearson correlation test showed a strong correlation of cytokine and chemokine productions for *M. smegmatis* and *M. agri* challenges (r=0.93, Table 2). Again, no positive correlations were observed for productions of different proteins in PHA challenge compared to either mycobacteria challenge (Table 2). Similar patterns of extracellular cytokine and chemokine productions in *M. smegmatis* and *M. agri* challenges suggested that cellular immune responses to these strains were the same. In contrast, different cytokine and chemokine expression patterns in PHA challenges indicated that PHA may have induced a distinct immune response.

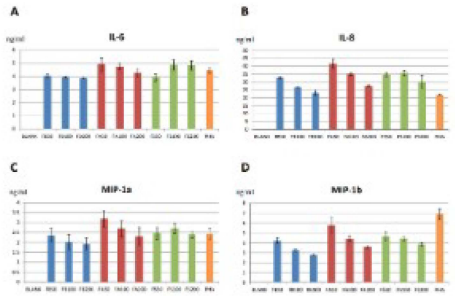

Figure 1: Extracellular cytokine and chemokine expressions in PBMC cultures challenged to *M. smegmatis* isolates. Concentrations of IL-6 (A), IL-8 (B), Mip-1α (C), and Mip-1β (D) in PBMC culture supernatants are shown. PBMC cultures were challenged to the following isolates of *M. smegmatis* from feline: FB, an abscess; FA, abdomen; FS, skin. Numbers 50, 100 and 200 next to the letters corresponded to 50 μg/ml, 100 μg/ml, or 200 μg/ml mycobacterial cells in PBMC challenges, respectively. PHA, the challenge to 10 μg/ml PHA; BLANK, the control PBMC culture.

Table 1: Spearman correlation coefficients of cytokine and chemokine expressions in PBMC challenges to *M. smegmatis* isolates.

	Cell concentration50 μg/ml			100 μg/ml			200 μg/ml
Challenge FB FA	**FS**	**FB**	**FA**	**F**	**FB**	**FA**	**F**
FB--	-		-	**S**		-	**S**
FA 0.75 -	-	0.7	-	-	0.9	-	-
FS 0.86 0.95	-	7	0.99	-	8	0.92	-
PHA -0.51 0.01	-0.03	0.8	-1	-	0.9	-0.61	-0.6
Note: Numbers in bold indicate strong positive correlations.		4		-1	8		
		-0.8			-0.6		

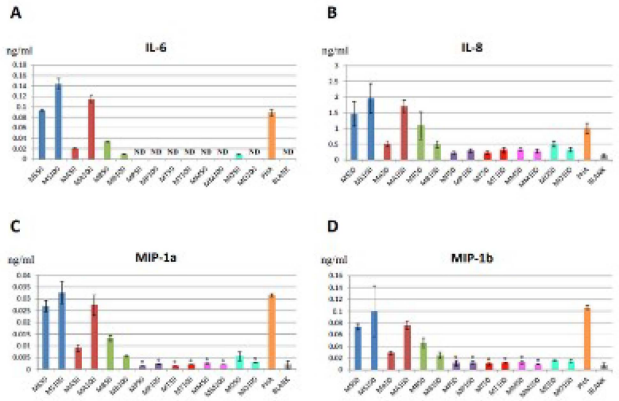

Figure 2: Extracellular cytokine and chemokine expressions in PBMC cultures challenged to various *Mycobacterium* strains. Concentrations of IL-6 (A), IL-8 (B), Mip-1α (C), and Mip-1β (D) in PBMC culture supernatants are shown. PBMC cultures were challenged to the following *Mycobacterium* strains: MS, *M. smegmatis;* MA, *M. agri;* MB, *M. brumae;* MP, *M. phlei;* MT, *M. tokaiense;* MM, *M. aurum;* MO, *M. obuense*. ND, not detected; o denotes no significant differences from the control cultures (BLANK).

Table 2: Spearman correlation coefficients of cytokine and chemokine expressions in PBMC challenges.

	Challenge MS100	MA100	BS100
MS100 -		-	-
MA100 0.93		-	-
	BS100 -0.32	-0.29	-
	PHA -0.93	-0.95	0.02

Note: Numbers in bold indicate strong positive correlations.

To further confirm that *M. smegmatis* and *M. agri* activated the same cytokine and chemokine expression profiles in immune cells, we challenged PBMC to the mixture of *M. smegmatis* and *M. agri* at 50 μg/ml each and compared cytokine and chemokine concentrations in the mixed challenge to their levels in individual challenges to 100 μg/ml bacterial cells. We hypothesized that if both *Mycobacterium* strains evoked the same immune response, exposures to the mixture of two strains would elevate the level of each protein to the value, which would be the average of two protein concentrations in individual challenges. Indeed, as shown in Figures 3A-3D, for all four analytes, each cytokine and chemokine concentration in PBMC cultures challenged to the mixture of two *Mycobacterium* strains was close to the average of their concentrations in individual challenges. The Z-test did not show any statistically significant differences between these two values for all four proteins. Our observation that the effects of *M. smegmatis* and *M. agri* challenges were not combined in the mixtures of those two strains suggested that the immune responses to these *Mycobacterium* strains were the same.

PBMC responses to *Mycobacterium* strains: Distinct from responses to *B. subtilis*

We also compared immune responses to *M. smegmatis* and *M. agri* to responses to other bacteria of distant classification lineages. The *Mycobacterium* genus contains species from Actinobacteria phylum. In contrast, *B. subtilis*, is a Gram-positive bacteria which belongs to the distant phylum Firmicutes. Previous studies showed that *B. subtilis* activated immune responses *in vivo* [18] and induced cytokine productions in PBMC cultures [19]. To compare cellular responses to *B. subtilis* with responses to *Mycobacterium* strains, we challenged PBMC cultures to various concentrations of heat-killed *B. subtilis* cell preparations and measured cytokine and chemokine levels in stimulated cultures. As shown in Figures 4A-4D, *B. subtilis* preparations at 100 μg/ml induced productions of IL-6, IL-8, MIP- 1α and MIP-1β at high levels. When cellular immune responses in *B. subtilis* challenges were compared with either *M. smegmatis*, *M. agri* or PHA challenges, it appeared that cytokine and chemokine productions in the *B. subtilis* challenge did not correlate with protein levels in other challenges (Table 2). Our results suggested that cellular responses to *B. subtilis* were distinct from responses to *Mycobacterium* strains or PHA.

Since challenges to *B. subtilis* resulted in distinct patterns of cytokine and chemokine productions, this strain may have engaged a different activation mechanism of cytokine and chemokine expressions than *Mycobacterium* strains. In this case, a combined *Mycobacterium* and *B. subtilis* challenge would have an additive effect on cytokine and chemokine levels. To test this, in challenges to 100 μg/ml bacterial preparations of either strain alone. Again, because higher concentrations of bacterial cells tend to suppress protein secretion (see Figure 1A), the "average" effect would indicate that these two strains activate the same cytokine and chemokine production pathway, while higher than average protein levels would indicate two different activation mechanisms. As shown in Figure 4A, the cultures challenged to the mixtures of *B. subtilis* and either *Mycobacterium* strain produced significantly higher IL-6 concentrations than the averages of two IL-6 concentrations in individual challenges (Figure 4A). However, significant differences in IL-8 and MIP-1β levels were observed only in the combined *B. subtilis* and *M. agri* challenge (Figures 4B-4D). Also, differences in MIP-1α levels for mixed challenges were not significant, which may be attributed to a higher variation in measuring concentrations of this cytokine (Figure 4C). Our results demonstrated that cellular responses to *B. subtilis* and *Mycobacterium* strains were different and their combination had higher than average effects on cytokine and chemokine production. We concluded that challenges to *B. subtilis* strains may elicit a distinct immune response pathway, thereby resulting in partially combined effects on extracellular cytokine and chemokine productions in mixed challenges.

Weak PBMC: Responses to other *Mycobacterium* strains were not due to cellular toxicity or immunosuppression

We were unable to detect significant PBMC responses to *M. phlei*, *M. tokaiense*, *M. aurum* and *M. obuense* (Figure 2A). We also observed decreases in cytokine and chemokine production at higher concentrations of *M. smegmatis* isolates (Figure 1A) and *M. brumae* (Figure 2A). This observation raised the possibility of cellular toxicity and/or immune suppression induced by these mycobacterial preparations. To confirm or rule out this possibility we added 50 μg/ml *Mycobacterium* strains to 50 μg/ml *B. subtilis* in PBMC challenges and determined if mycobacterial cell preparations suppressed immune responses to *B. subtilis*. As shown in Figure 5A, addition of any *Mycobacterium* to *B. subtilis* in PBMC challenges did not inhibit cytokine and chemokine productions. We also observed significant increases in protein levels in response to the *M. brumae* mixure, consistent with elevated responses to this *Mycobacterium* strain (Figure 2A). Concentrations of IL-6 and MIP-1α also increased for the *M. phlei* mixture (Figures 5A and 5B) and a significant elevation of IL-6 levels was observed when *M. tokaiense* was added to the *B. subtilis* challenge (Figure 5A). In contrast, there was a slight statistically significant decrease in IL-8 concentrations for the *M. obuense* mixture (Figure 5C), consistent with the suppression of the immune response seen at the higher concentration of this strain (Figure 2A). We therefore concluded that that the lack of immune activities of *Mycobacterium* strains in PBMC challenges was not due to the concomitant cellular toxicity or immunosuppression induced by these bacterial preparations at concentrations tested.

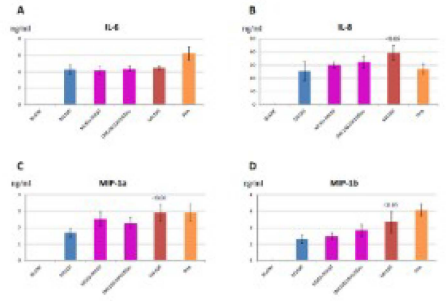

Figure 3: PBMC responses to the mixtures of *M. smegmatis* with *M. agri*. Concentrations of IL-6 (A), IL-8 (B), Mip-1α (C), and Mip-1β (D) in PBMC cultures are shown. MS+MA, PBMC challenge to the mixture of 50 μg/ml *M. smegmatis* and 50 μg/ml *M. agri*. (MS,MA)av, the average of two protein concentrations in individual challenges to either 100 μg/ml *M. smegmatis* (MS100) or 100 μg/ml *M. agri* (MA100). The numbers above the bars denote p-values for differences in protein concentrations in the individual challenges (MA100 *vs.* MS100).

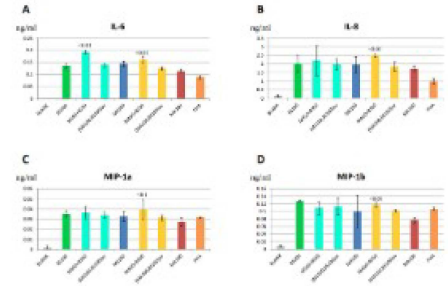

Figure 4: PBMC responses to the mixtures of *B. subtilis* with either *M. smegmatis* or *M. agri*. Concentrations of IL-6 (A), IL-8 (B), Mip-1α (C), and Mip-1β (D) in PBMC cultures are shown. PBMC cultures were challenged to the following strains: BS100, 100 μg/ml *B. subtilis*; MS50+BS50, the mixture of 50 μg/ml *M. smegmatis* with 50 μg/ml *B. subtilis*; MA50+BS50, the mixture of 50 μg/ml *M. agri* with 50 μg/ml *B. subtilis*. (MS100,BS100)av, the average of two protein concentrations in individual challenges to either 100 μg/ml *M. smegmatis* or 100 μg/ml *B. subtilis*. (MA100,BS100)av, the average of two protein concentrations in individual challenges to either 100 μg/ml *M. agri* or 100 μg/ml *B. subtilis*. The numbers above the bars denote p-values for increases in protein concentrations in combined challenges *vs.* the averages of two concentrations in individual challenges.

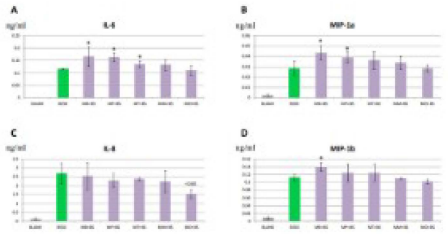

Figure 5: PBMC responses to combinations of *B. subtilis* with various *Mycobacterium* strains. Concentrations of IL-6 (A), IL-8 (B), Mip-1α (C), and Mip-1β (D) in PBMC cultures are shown. PBMC were challenged to the mixtures of 50 μg/ml *B. subtilis* with one of the following strains: BS50, none; MB+BS, 50 μg/ml *M. brumae*; MP+BS, 50 μg/ml *M. phlei*; MT+BS, 50 μg/ml *M. tokaiense*; MM+BS, 50 μg/ml *M. aurum*; MO+BS, 50 μg/ml *M. obuense*. Asterisks indicate statistically significant increases in protein concentrations in combined challenges *vs.* the BS50 challenge. The number above the bar denotes the p-value for a decrease in IL-8 concentration in the combined MO+BS challenge *vs.* the BS50 challenge.

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DISCUSSION

We sought to identify potential immune-modulating properties of multiple *Mycobacterium* species in a heat-killed format in an effort to determine if inherent characteristics of these mycobacteria have the capacity to act in a productive immune-modulating fashion. Previous analyses of immune-modulating activities of 88 *Mycobacterium* strains provided useful insights regarding the utility of various strains as potential candidates for immunotherapy of cancer in reference to their pathogenicity and growth rate [2]. However, the use of the monocytic cell line for immune challenges and a limited number of immune parameters measured in this study, namely IL-12 and TNF-α, limited its applications. In the current study we evaluated the immune-stimulating properties of seven *Mycobacterium* strains using PBMC cultures from healthy donors and compared them to the responses to *B. subtilis* strain.

We measured the production of the cytokine IL-6 and, as well as the chemokines IL-8, MIP-1α and MIP-1β in immune challenges, which were the parameters previously measured in our fibromyalgia studies [17,20]. We identified two *Mycobacterium* strains, *M. smegmatis* and *M. agri* to be the most effective in inducing PBMC immune responses. It has been shown that *M. smegmatis* preparations induce a potent immune response [21], display high anti-tumor activity in a mouse model [22] and were effective in cancer immunotherapy studies [23]. Consistent with the results of our study, live *M. smegmatis* cells were capable of inducing the production of IL-6, IL-8 and other cytokines in neutrophil cultures [9].

M. brumae is yet another promising candidate for immunotherapy. High anti-tumor and immune-modulatory activities of this *Mycobacterium* strain has been demonstrated [24]. However, our results showed only moderate PBMC responses to this strain compared to *M. smegmatis* and *M. agri* (Figure 2A). The production of the cytokine IL-6 and the chemokine IL-8 by immune cells in response to *M. brumae* were in agreement with previously reported studies [12,25].

The absence of immune responses to *M. phlei*, *M. tokaiense*, *M. gurum* and *M. obuense* strains was somewhat surprising since these *Mycobacterium* strains showed significant TNF-alpha and IL-12 stimulation activities in a cultured cell line [2]. *M. obuense* and *M. phlei* were active ingredients of vaccine preparations

The release of specific chemokines and cytokines can be especially valuable as it concerns diseases where immune deficiency exists, such as fibromyalgia, interstitial cystitis and chronic pain. If an immune-modulating intervention pathway were to be identified, various modalities of therapy with non-pathologic organisms could be achieved, thereby limiting any potential risk for adverse side effects. Sites of action can include various microbiomes including, but not limited, to the microbiome of the gastrointestinal tract and of the vagina. Mycobacterial preparations are generally safe and well tolerated [28,29]. Resultantly, the benefits of such interventions can act in a positive fashion without generating significant risks.

CONCLUSION

We identified *M. smegmatis* and *M. agri* as the most effective *Mycobacterium* species for inducing immune responses rendering these *Mycobacterium* preparations to be the most promising candidates for immunotherapy. Our results suggested that *Mycobacterium* strains and *B. subtilis* evoked distinct immune responses and have different impacts on the immune system. The distinct immune-modulating effects of *Mycobacterium* strains and *B. subtilis* may have potential implications for immunotherapy of cancer as well as the treatment of immune deficiency disorders. Our methodology for comparing immune responses for various strains may provide a useful tool for studying immune effects of various bacterial species.

ACKNOWLEDGEMENTS

We wish to thank Dr. Franzblau and Enock Mpofu from the Institute for Tuberculosis Research, College of Medicine at the University of Illinois at Chicago for providing *M. smegmatis* strain isolates and growing mycobacteria as well as preparing mycobacterial specimens for this study.

CONFLICT OF INTERESTS

The authors declare no conflict of interests.

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EXHIBIT B

Dear XX,

In [insert year], you ordered the FM/a Test from EpicGenetics, Inc., which test EpicGenetics sold as a blood test for diagnosing fibromyalgia and/ or "immune deficiency disease". We are writing to inform you that we recently settled a lawsuit related to the marketing of claims made about the FM/a Test.

The lawsuit was filed in the District of Columbia Superior Court by the Center for Science in the Public Interest ("CSPI"). The lawsuit alleged that EpicGenetics made certain false or misleading statements about the efficacy of the FM/a Test. It also alleged that EpicGenetics made false or misleading claims about the ability of individuals who tested positive for fibromyalgia and/ or "immune deficiency disease" to participate in experimental treatment trials testing treatments for the disease. EpicGenetics denied and continues to deny any wrongdoing or liability to CSPI.

As you may know, the FM/a Test diagnosed fibromyalgia, an immune deficiency disease. There is a connection between fibromyalgia and DNA abnormalities. Fibromyalgia can result in certain symptoms, such as chronic fatigue and pain. People with such symptoms may be a good candidates for the FM/a Test or similar tests, such as the BSURE Test, which is currently available.

Although EpicGenetics denied the material allegations in the Complaint, to avoid the risks and costs associated with protracted litigation, EpicGenetics decided to settle the lawsuit.

As part of the Settlement Agreement, EpicGenetics agreed to discontinue the sale of the FM/a Test and agreed to certain marketing restrictions on advertising a similar and still available test, the BSURE Test. EpicGenetics also agreed to send this letter to patients and doctors who ordered the FM/a Test in the District of Columbia informing them of the Settlement Agreement.

Enclosed is a copy of the Complaint and Settlement Agreement.

Thank you,
XXX

EXHIBIT C

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA
CIVIL DIVISION

CENTER FOR SCIENCE IN THE PUBLIC INTEREST, on behalf of the interests of District of Columbia consumers, Plaintiff, v. EPICGENETICS, INC., Defendant.	Case No. 2023-CAB-006126 Judge Juliet J. McKenna Next Event: Initial Scheduling Hearing Aug. 23, 2024, 9:30 am

Stipulation of Dismissal with Prejudice

Plaintiff Center for Science in the Public Interest and Defendant EpicGenetics, Inc., by and through their undersigned counsel of record, stipulate that pursuant to Civil Rule 41(a)(1)(A)(ii), Plaintiff dismisses the above-captioned matter with prejudice. Except as otherwise provided for by the Parties, all costs and fees arising out of this action are waived by the Parties.

Date: Aug. __, 2024

Respectfully submitted,

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