IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

LEONARD G. HOROWITZ,
Plaintiff,

vs. Case No. 2:20-cv-00955-JLB-NPM

PFIZER INC., et al.,
Defendants.
_____/

PLAINTIFF'S MOTION FOR JUDICIAL NOTICE OF PUBLIC RECORDS IN SUPPORT OF OPPOSITION TO DEFENDANT MODERNA'S MOTION TO DISMISS AND INCORPORATED MEMORANDUM OF LAW

LEONARD G. HOROWITZ
Plaintiff, pro se
Post Office Box 150457
Cape Coral, Florida 33915
310-877-3002
editor@medicalveritas.org

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

LEONARD G. HOROWITZ,
Plaintiff,

vs. Case No. 2:20-cv-00955-JLB-NPM

PFIZER INC., et al.,
Defendants.
_____/

PLAINTIFF'S MOTION FOR JUDICIAL NOTICE OF PUBLIC RECORDS IN SUPPORT OF OPPOSITION TO DEFENDANT MODERNA'S MOTION TO DISMISS AND INCORPORATED MEMORANDUM OF LAW

Plaintiff Horowitz ("Plaintiff"), pursuant to Federal Rule of Evidence 201, respectfully requests this Court take judicial notice of four public records, three issued by the Department of Defense's Defense Advanced Research Programs Agency ("DARPA"), and the fourth from the Massachusetts Institute of Technology, filed here in support of Plaintiff's Opposition to Defendant Moderna's (and Pfizer's) Motion(s) to Dismiss; validating Article III federal jurisdiction pursuant to Plaintiff's 42 U.S.C. §§ 1981 and 1983 claims, and demonstrating "the existence of a genuine factual issue regarding the satisfaction of § 1983's state action requirement." *Focus on the Family v. Pinellas Suncoast Transit*, 344 F. 3d 1263 - Court of Appeals, 11th Circuit 2003.

INTRODUCTION

On December 3, 2020, Plaintiff filed a Complaint against Defendants Moderna, Pfizer, Henry Schein, and Hearst, claiming unfair and deceptive trade

practices by the Defendants damaging the Plaintiff's reputability and sales of "OxySilver with 528" that competes against Defendants' interests in vaccines, antibiotics, and secular healthcare narrative. A civil conspiracy claim was made thusly: "297. The Defendants, complicit scammers, and allied insiders in government thereby discouraged consumers and government officials from relying on competing products, such as the anti-oxidants hydroxychloroquine and the Plaintiff's OxySilver™. 298. The aforementioned overt acts damaged the Plaintiff and society." The Plaintiff also claimed for Injunctive Relief stating: "323. Plaintiff is also a Levitical priest who recognizes the religious implications of forced vaccinations and lockdowns violating Constitutional freedoms of religious assembly and Bible laws requiring blood purity for the protection of genetic integrity. . . . 334. The injunction should require Defendants to cease and desist disparaging and defaming the Plaintiff/whistleblower on the aforementioned forums and elsewhere."

Now Defendants seek to dismiss this action before discovery commences, falsely alleging the Plaintiff is simply a "conspiracy theorist" making wild accusations. Defendants divert from the personal and commercial damage they caused to the Plaintiff's reputability and OxySilver sales, respectively. Damage they presently compound by continuing to smear and discredit the Plaintiff as Defendant Pfizer has done in its Motion to Dismiss, and Motion for Judicial Notice

of Public Records that conceal the complete FDA record exonerating the Plaintiff following contested allegations of drug advertising pursuant to OxySilver's online description.

The Defendants also falsely argue to dismiss the Complaint claiming their "safe harbor" protection against liability under Fla. Stat. § 501.204(1). But that statute only creates "safe harbor" when "[a]n act or practice required [by government] or specifically permitted by federal or state law" is committed. Therefore, that "safe harbor" *does not apply to* Moderna's act and practice of allegedly converting, concealing, and/or smearing Plaintiff's 528 intellectual and industrial property as the "least restrictive" methods of achieving the government's goals; nor obfuscating Moderna's and Pfizer's nano-metal hydrogels' and their risks to society, public health and safety, juxtaposed against OxySilver's superior competitive safety.

These matters are material to Plaintiff's claims of unfair competition and deceptive trade since Defendants': (a) vaccine hydrogels delivering mRNA to cells directly compete against the Plaintiff's "OxySilver™ with 528" product. Both are bioelectrically-active nano-metal anti-microbials; and (b) lacking genetic safety testing protocols precluding competent appraisal by the FDA, thus unfair competition by federal actors in securing Defendants' markets, restricting OxySilver™ competition, thus damaging the Plaintiff's OxySilver sales and benefits to society.

Moreover, the Defendants falsely argue the Plaintiff's civil rights claims under 42 U.S.C. §§ 1981 and 1983 are precluded by the supposed absence of state actors.

Accordingly, Plaintiff hereby requests this Court to take judicial notice of the state actors Moderna engaged by appraising the following four (4) federal agency records evidencing the government's financing and joint venturing between Moderna (GSK/Pfizer) and DARPA in the development of Moderna's (and Pfizer's) "novel" COVID-19 vaccine hydrogel device that mimics the fundamental bioelectronics of "OxySilver™ with 528," and enables the "genetic therapy" claimed by Moderna to be the function of its vaccine.

In addition, one (two-page) M.I.T. Langer Lab screenshot attached hereto proves Moderna's leading scientist, board member, and financial agent, pioneered the research and development of Moderna's bioelectric, electromagnetic, ultrasonic wave frequency generating hydrogel technology for use in "Creating new approaches for delivering drugs such as proteins and genes across complex barriers in the body such as the blood-brain barrier, . . ." This biotechnology is important for Judicial Notice because it has been generally concealed from public discourse. This concealment enables Moderna's man-made modified "mmRNA vaccine" to potentially administer far more than what Moderna or the company's Hearst media, First Databank, and McKesson Company partners admit about OxySilver's competition. These public records include:

1. Defense Advanced Research Projects Agency ("DARPA") electronic mail of September 18, 2020, providing the first public notice that the Department of Defense is investigating "Moderna Therapeutics' (Moderna) alleged failure to disclose DARPA funding support in its patented inventions."
    a. This record is publicly available on the complainant's website: https://www.keionline.org/wp-content/uploads/DARPAresponse-KEI-Moderna-18Sep2020.pdf

2. Defense Advanced Research Projects Agency ("DARPA") public announcement of the "Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT)" program from which financial and administrative support for Moderna's vaccine derives: "to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. . . . [including] novel methods for rapidly manufacturing new types of vaccines with increased potency; novel tools to engineer mammalian cells for targeted drug delivery and in vivo diagnostics; and novel methods to impart near-immediate immunity to an individual using antibodies."

   a. This record is publicly available on the DARPA website: https://www.darpa.mil/program/autonomous-diagnostics-to-enable-prevention-and-therapeutics

3. Defense Advanced Research Projects Agency ("DARPA") "COVID-19" review of DARPA's work with "its academic and industry partners, to provide technical and scientific solutions to address the COVID-19 pandemic." Review includes the "ADEPT/P3" program to "deliver genes that encode the antigen and allow the human body to produce the antigen from its own cells, triggering a protective immune response. In December 2020, former ADEPT performer Moderna's RNA vaccine received FDA Emergency Use Authorization (EUA) approval . . ." And "a human monoclonal antibody (mAB) identified as part of the P3 program and in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID) . . . being developed in collaboration with Eli Lilly and Company . . . to be evaluated together with VIR-7831, an antibody developed by Vir Biotechnology, Inc. and GlaxoSmithKline (Pfizer's parent company, as a potential COVID-19 therapy . . ."

4. M.I.T. Langer Lab website detailing the "Research Overview" of Moderna's chief scientist and financing agent, Robert Langer, in "Developing controlled release systems [for drugs and vaccines] that can be magnetically, ultrasonically, or enzymatically triggered to increase release rates. . . . Creating new approaches for delivering drugs such as proteins and genes across complex barriers in the body such as the blood-brain barrier . . ."

   a. This record is publicly available on the M.I.T. Langer Lab website: https://langerlab.mit.edu/

MEMORANDUM OF LAW

(Prepared by and quoted from Pfizer's Counsel, Brian T. Guthrie)

"Federal courts may take judicial notice of any fact "not subject to reasonable dispute because it … can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2).

"In the Eleventh Circuit, courts routinely find that the public records of federal agencies, including FDA, satisfy Rule 201 and consider those records at the motion to dismiss stage. *E.g.*, *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 754–56 (11th Cir. 2011)(relying upon FDA-approved package inserts to decide motion to dismiss); *Leroy v. Medtronic, Inc.*, 2015 WL 4600880, at *5 (N.D. Fla. July 29, 2015) ("Courts in this circuit and elsewhere have taken judicial notice of similar FDA public records under similar circumstances, and without transforming a motion to dismiss under Rule 12(b)(6) into a motion for summary judgment."); *Stanifer v. Corin USA Ltd., Inc.*, 2014 WL 5823319, at *3 (M.D. Fla. Nov. 10, 2014) (considering FDA records on a motion to dismiss because "public records available on the FDA's website . . . satisfy the requirements of Rule 201"); *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1189 n.2 (M.D. Fla. 2013) (taking "judicial notice of public records of the FDA" on a motion to dismiss); *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013).

"Other courts have taken judicial notice of the same or similar FDA documents identified by Pfizer here. *E.g.*, *Goico v. U.S. Food & Drug Admin.*, 2020 WL 7078731 (D. Kan. Dec. 3, 2020). In *Goico*, a *pro se* plaintiff sued to enjoin FDA from restricting access to the drug hydroxychloroquine after the Agency revoked the drug's emergency use authorization ("EUA") for COVID-19 treatment. At the Agency's request, the court took judicial notice of five documents publicly available on the FDA website at the motion to dismiss stage, including the EUA for Chloroquine, FDA News Release, and FDA Risk Alert. *Id.* at *3.2

"This Court should likewise take judicial notice of the six public records offered by Pfizer, which are similar to the FDA records judicially noticed in *Goico*. Here, Pfizer requests that this Court take judicial notice of FDA's public health emergency determination and emergency use authorization declaration,3 the Pfizer vaccine's EUA, FDA's review memorandum, FDA guidance documents addressing EUAs, and a warning letter sent by FDA to Plaintiff in 2010. Taking judicial notice of each document is appropriate under Rule 201, as each is readily available on the U.S. Federal Register or FDA's websites, both of which constitute "a source that cannot

reasonably be questioned." *Dixon v. Allergan USA, Inc.*, 2015 WL 13777064, at *2 (S.D. 2 The Fla. Apr. 2, 2015) (stating "FDA's public records merit judicial notice" because they are "readily accessible on the FDA's website, a source that cannot reasonably be questioned"); *accord Leroy*, 2015 WL 4600880, at *5."

CONCLUSION

For all of these reasons, Plaintiff respectfully requests this Court take judicial notice of the four public records identified herein, attached as Exhibits 1 thru 4, supplementing Plaintiff's Opposition to Defendant Moderna's Motion to Dismiss filed April 12, 2021, and supporting Plaintiff's pending Opposition to Defendant Pfizer's Motion to Dismiss.

LOCAL RULE 3.01(g) CERTIFICATION

Pursuant to Local Rule 3.01(g), the undersigned pro se Plaintiff conferred with Moderna about the Judicial Notice requested herein. Defendant Moderna opposes this Motion as currently filed.

Respectfully submitted.

DATED: April 15, 2021

/s Leonard G. Horowitz
Plaintiff, pro se

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of April 2021, I filed a true and correct copy of the foregoing "Motion for Judicial Notice" including Exhibits 1 thru 4, with the Court's Clerk for customary E-filing. I further certify that I served by E-Mail a copy of the filed document to the following participant(s):

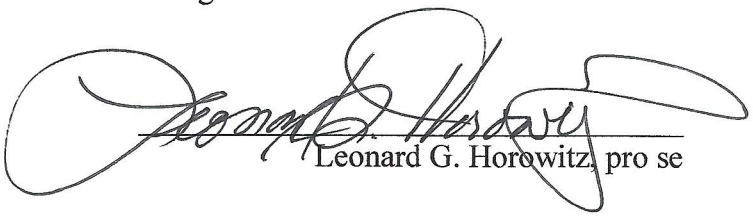
ATTORNEY FOR HENRY SCHEIN, INC.
Thomas J. Cunningham
LOCKE LORD LLP
777 South Flagler Drive
East Tower, Suite 214
West Palm Beach, FL 33401
T: 561- 833-7700
http://Tcunningham@lockelord.com

ATTORNEY FOR PFIZER INC.
Brian T. Guthrie, Esquire
SHOOK, HARDY & BACON L.L.P.
100 N. Tampa St., Suite 2900
Tampa, Florida 33602
T: 813-202-7100 | F: 813-221-8837
E: bguthrie@shb.com
lcintron@shb.com
lmaranto@shb.com

ATTORNEY FOR MODERNA INC.
Nilda M. Isidro
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue New York, NY 10018
T: 212-459-7224 | F: 646-558-4208

ATTORNEY FOR HEARST CORP.
Legal Department
Hearst Tower in Manhattan
300 West 57th Street and 959 Eighth Avenue,
New York, NY 10019
T: 212-649-2000

HONORABLE JUDGE JOHN BADALAMENTI
HONORABLE MAGISTRATE NICHOLAS MIZELL
United States District Court
for the Middle District of Florida
Ft. Myers Division U.S. Courthouse & Federal Building
2110 First St, Fort Myers, FL 33901
T: 239-461-2000



Leonard G. Horowitz, pro se

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY
675 NORTH RANDOLPH STREET
ARLINGTON, VA 22203-2114

September 18, 2020

Via Electronic Mail

James Love
Knowledge Ecology International
1621 Connecticut Avenue, NW, Suite 500
Washington, D.C. 20009

Dear Mr. Love:

I am responding to your letter of August 27, 2020, to Dr. Amy Jenkins at the Defense Advanced Research Projects Agency (DARPA) requesting the Department of Defense investigate Moderna Therapeutics' (Moderna) alleged failure to disclose DARPA funding support in its patented inventions. DARPA is reviewing agreements it has awarded to Moderna and U.S. patents and published patent applications for Moderna and ModernaTx, since March 2013.

Thank you for bringing this matter to our attention. Should you have any questions, please contact DARPA Deputy General Counsel, Geraldine Chanel, at 571-218-4609 or geraldine.chanel@darpa.mil.

Sincerely,

D. Peter Donaghue
Contracting Officer-Division Director
Contracts Management Office

Exhibit 1

DEFENSE ADVANCED
RESEARCH PROJECTS AGENCY

Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT)

Dr. Amy Jenkins

The Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program supports individual troop readiness and total force health protection by developing technologies to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. A subset of ADEPT technologies specifically support use by personnel with minimal medical training, delivering centralized laboratory capabilities even in the low-resource environments typical of many military operations. The program is part of a portfolio of DARPA-funded research aimed at providing options for preempting or mitigating constantly evolving infectious disease threats.

The ADEPT program's four thrusts cover simple-to-use, on-demand diagnostics for medical decision-making and accurate threat-tracking; novel methods for rapidly manufacturing new types of vaccines with increased potency; novel tools to engineer mammalian cells for targeted drug delivery and in vivo diagnostics; and novel methods to impart near-immediate immunity to an individual using antibodies.

ADEPT has pioneered use of nucleic-acid-based anti-infective technologies, valuable for their efficacy and adaptability. These tools—primarily coded genetic instructions to the body on how to produce its own protective antibodies against a specific threat—have the advantages of being easily manufactured at scale using largely synthetic processes, transported and stored without many of the cold-chain logistics required by traditional medical countermeasures, delivered with near-immediate efficacy, and safely expressed in the body for only a limited duration, causing no permanent alteration to the genome.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

COVID-19

Title: The DARPA Difference: Pivoting to Address COVID

Updated March 19, 2021

DARPA continues to work closely with the Department of Defense (DoD), multiple U.S. government agencies, as well as its academic and industry partners, to provide technical and scientific solutions to address the COVID-19 pandemic.

Welcome to the sixth installment of DARPA's ongoing web series highlighting the agency's active programs focused on the diagnosis, detection, treatment, prevention and manufacture of medical countermeasures to combat COVID-19, including:

Diagnose & Detect:

Diagnosis is a critical aspect of pandemic prevention and response. DARPA research is producing tests that offer earlier, more sensitive, and widely distributable diagnosis of SARS-CoV-2-infected patients.

DARPA began the Detect It with Gene Editing Technologies (DIGET) and the Epigenetic CHaracterization

EXHIBIT 3

and Observation (ECHO) programs focused on rapid discovery, validation, and manufacture of diagnostics detecting any threat, anytime, anywhere.

DIGET, which recently awarded a contract to MRI Global, is moving forward with its goal to build a multiplexed detection device to screen up to a thousand pathogens at a time, along with a mobile, point-of-need device targeting up to 10 pathogens, including SARS-CoV-2. DARPA's ECHO program is developing diagnostic tests that measure the body's response to viral infection rather than testing for the virus itself.

DARPA ECHO supported the U.S. Marine Corps and the Naval Medical Research Center as part of COVID-19 Health Action Response for Marines (CHARM). During the 2-month study, DARPA provided near-real-time diagnostic results for over 3,500 Marine recruits to ensure that training at Parris Island could continue through the entirety of 2020 and into 2021. This work led to updated CDC quarantine guidelines reducing the necessary quarantine period from 14 to 10 days for individuals testing positive for COVID-19, as outlined in a November 2020 New England Journal of Medicine publication.

A second CHARM study was posted in January 2021 on the preprint server MedRxiv, demonstrating that COVID-19 reinfection was "common" among those who had the virus. Of the 189 participants that tested positive for antibodies, 19 ended up testing positive for the virus six weeks later, according to the study. In March 2021, the study was accepted for publication in The Lancet.

The team is now focusing on expanding the cohort and tracking long-term host response, in addition to new infections, in the U.S. Marine Corps.

In a separate December 2020 investigation, ECHO performers at Duke University posted data on chromatin remodeling reflecting disease severity prognosis, and a separate team at Stanford demonstrated 87.5% accuracy in predicting mortality in COVID. These studies demonstrated the potential of the epigenome to both diagnose and predict disease severity in COVID-19 patients at the early, asymptomatic stages of infection.

In addition to the host-based methods under development, in August 2020, ECHO performers received EUA approval for a direct viral saliva test, the first manufacturer's EUA for diagnosis of COVID-19 from saliva. The saliva test is now being further developed in partnership with the NIH RADx program.

Friend or Foe

Two preliminary efforts associated with the Friend or Foe program have made critical advances in SARS-CoV-2 detection.

A preliminary effort at the University of Illinois at Urbana-Champaign (UIUC), tasked with developing systems to detect pathogenic bacteria quickly, shifted to target COVID-19. Leveraging digital design and rapid prototyping on production manufacturing systems, the team demonstrated a point-of-care assay and system that requires only a smartphone to collect and process diagnostic images. The UIUC performer detected SARS-CoV-2 from nasal swab samples in 30 minutes, and developed test cartridges that can quickly scale up to hundreds of thousands of tests.

Researchers at Stanford University are developing biosensors that can quickly spot an attack on a cell

membrane – the first step of CoVID-19 (or any) infection. The team is using the platform to identify mechanisms to inhibit CoVID-19 membrane attack; the technology can be readily multiplexed enabling fast high-throughput drug screens.

Treat & Prevent:

DARPA technology contributes to preventing future COVID-19 infections through novel vaccine technology and more pervasive environmental aerosol monitoring, and to treating the disease through novel antibody treatments, rapid drug discovery, and domestic active pharmaceutical ingredient manufacture.

ADEPT/P3

As part of the ADEPT program in 2011, DARPA began investing in nucleic acid vaccines. The hypothesis was that rather than delivering antigens to the immune system, we could deliver genes that encode the antigen and allow the human body to produce the antigen from its own cells, triggering a protective immune response. In December 2020, former ADEPT performer Moderna's RNA vaccine received FDA Emergency Use Authorization (EUA) approval for the prevention of COVID-19.

In FY2016, DARPA initiated the Pandemic Prevention Platform (P3) program aimed squarely at the rapid discovery, testing, and manufacture of antibody treatments to fight any emerging disease threat. P3 convincingly demonstrated how to find and manufacture antibodies in less than 90 days (vs. years), using influenza, Zika, and MERS as test cases. As the COVID-19 outbreak began early in 2020, P3 research pivoted to address the novel coronavirus.

In November, 2020, AbCellera announced that a human monoclonal antibody (mAb) identified as part of the P3 program and in conjunction with the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center (VRC), bamlanivimab (LY-CoV555), had been granted emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the treatment of patients 12 years of age and older with mild to moderate COVID-19 to prevent hospitalization. AbCellera was able to obtain a sample of blood at the end of February 2020 via an intergovernmental panel, and identified over 1,000 potential antibody candidates. The mAb is being developed in collaboration with Eli Lilly and Company.

On January 21, 2021 the company announced that bamlanivimab reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities by up to 80%. This was followed by a second announcement six days later that the mAb will be evaluated together with VIR-7831, an antibody developed by Vir Biotechnology, Inc., and GlaxoSmithKline, as a potential COVID-19 therapy in low-risk patients with mild to moderate COVID-19. In February, 2021, bamlanivimab, administered with etesevimab also received an EUA for the treatment of mild to moderate COVID-19 in patients aged 12 and older who are at high risk for progressing to severe COVID-19 and/or hospitalization.

A second antibody drug (AZD7442) discovered by Vanderbilt University Medical Center and licensed to AstraZeneca is in late stage clinical studies to prevent covid-19 disease, and performers at Duke University are aiming for clinical studies this year for their highly potent antibody targeting the receptor binding domain of SARS-CoV-2which will be delivered as an mRNA construct.

SIGMA+

The DARPA SIGMA+ program is developing networked sensors to detect a variety of chemical, biological, and explosive threats. Some of this research has tilted to addressing the COVID-19 pandemic.

As part of this program, Battelle Memorial Institute developed a unique signature for the SARS-CoV-2 virus using their Resource Effective Bio-identification System (REBS). The REBS platform is designed to monitor the atmosphere for the presence of biological warfare agents and other pathogens using a technique called Raman spectroscopy. The effort worked to develop a signature for the virus that causes COVID-19 over the last year. This signature is currently being evaluated in several trials that utilize the REBS system and newer REBS+ system that provide a range of performance improvements compared to original REBS systems. This includes sampling times reduced from 30 minutes to just seconds.

The program is also evaluating the potential use of wearable technology to detect COVID-19 and other infectious diseases. The effort, led by RTI International and supported by Garmin® International, Inc., includes a number of studies on whether wearables can provide indications of infection based on an individual's immune response. One such study will track the health of U.S. Navy sailors living in close quarters aboard a ship via a novel "app" to monitor high quality wearable data. The app allows for continuous data collection in areas with limited or no access to Wi-Fi or cellular networks.

In addition to SIGMA+, the new SenSARS Disruptioneering Opportunity seeks to develop high performance, airbreathing pathogen sensors for SARS-CoV-2 and beyond, targeting use in offices, classrooms and buildings. The effort will examine new high sensitivity and high specificity signatures for SARS-CoV-2, and use those signatures to produce technology readiness level 4 sensor prototypes.

Panacea

Previously FDA-approved drugs are a second option that could be immediately repurposed as effective treatments. DARPA developed several screening methods to rapidly identify the best previously approved drugs including rapid tests on human organ-on-a-chip systems, identification of drugs that target SARS-CoV-2 interactions with human cells rather than targeting the virus itself, and the use of AI and machine learning methods to design and screen drugs.

The DARPA Panacea program generated and published the first human: SARS-CoV-2 protein interactome map in the journal *Nature*, which describes how the SARS-CoV-2 proteins interact with human cells. Developed by performers at performers at UCSF's Quantitative Bioscience Institute (QBI) and the Icahn School of Medicine at Mt. Sinai (ISMMS), this map has been used worldwide in the fight against COVID-19. The drug zotatifin, a protein synthesis inhibitor identified by the Panacea performers with their interactome map, is entering a Phase 1 clinical trial in Q1FY21 with investment support from the Defense Health Agency.

In January 2021, these performers published findings in *Science* demonstrating that Plitidepsin, a compound originally discovered in Mediterranean sea squirts, currently used as a therapeutic for the treatment of multiple myeloma, is 27.5-fold more potent against SARS-CoV-2 than remdesivir in vitro. Remdesivir received FDA emergency use authorization in 2020 for the treatment of COVID-19.

INTERCEPT

Researchers at Los Alamos National Laboratory (LANL), supported by DARPA's INTERCEPT program, are modeling in-person and population-based spread of COVID-19 by combining clinical data and mathematical modeling to provide a quantitative understanding of the SARS-CoV-2 infection process within infected individuals and derive principles for therapeutic treatments for the purpose of limiting spread, reducing disease severity, and minimizing the risk of resistance. In a manuscript published in Clinical Pharmacology & Therapeutics, the researchers review current literature on using within-host models to understand SARS-CoV-2 infection dynamics and their relationship with infectiousness, immune responses, and disease severity. This work provides an up-to-date synthesis of what is known about quantitative SARS-CoV-2 viral dynamics and their implication to both non-pharmaceutical and pharmaceutical interventions, such as therapeutics and vaccines.

Another INTERCEPT performer, Autonomous Therapeutics, Inc (ATI), is developing therapeutics to provide protection against any coronavirus – from novel mutational strains of COVID-19 to the next (unpredictable) threat. Known as Therapeutic Interfering Particles (TIPs), these broad-spectrum antivirals can be developed and stockpiled before the next threat emerges or is even known. TIP development is being supported by the INTERCEPT effort, with additional backing for clinical transition from leading private investors and a partnership with BARDA and Johnson and Johnson known as Blue Knight.

ATI is also developing non-invasive platform technologies to enable the at-home, self-administered distribution of next-generation, gene-encoded antivirals. The technology would surmount a major barrier to the distribution of leading vaccine and monoclonal antibody approaches, which require intramuscular (IM) or intravenous (IV) delivery in centralized clinical settings.

PREPARE

On February 3, 2021 a PREPARE performer team at Georgia Tech and colleagues published a paper in *Nature* highlighting a new mRNA treatment as a potential therapeutic against both influenza A virus and SARS-COV-2 using Cas13a constructs they developed as part of the program.

Manufacture:

The COVID-19 pandemic has highlighted vulnerabilities in the U.S. pharmaceutical supply chain. Work being done under DARPA's Make-It program furthers the development and commercialization of technology that directly addresses these vulnerabilities to enable an end-to-end, deployable and scalable capability for the production of medicines made from readily available commodity materials that can be sourced within the U.S.

AMD performers are collaborating with the Walter Reed Army Institute of Research (WRAIR) to apply artificial Intelligence (AI) techniques to accelerate the discovery of drugs to combat SARS-CoV-2. Under this program, the NIH National Center for Advancing Translational Sciences (NCATS) and WRAIR provide medicinal chemistry expertise to MIT and SRI, and also conduct in vitro testing of the AI predictions to validate and inform the models.

Researchers at MIT are concentrating efforts on the development of new AI algorithms that specifically

address the problem of data scarcity inherent in studying a novel virus, and are looking to apply such techniques to identify synergistic combination therapies in the future. They recently posted blog posts on results from their model trained to predict antiviral activity against COVID-19, and efforts towards the development machine-learning tools to aid in identifying molecules with therapeutic effects against the disease.

AMD performers at SRI International are developing AI tools that incorporate chemists' expert knowledge, in addition to that learned through data, to discover analogs of existing therapeutics with potency against SARS-CoV-2. They have also recently published data on the use of machine learning models to identify inhibitors of the virus.

Make-It

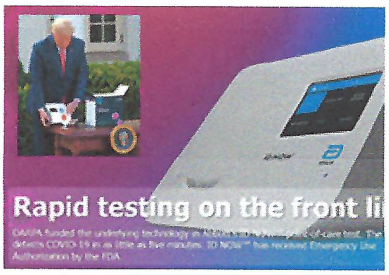
Under Make-It, Active Pharmaceutical Ingredient (API) production was further automated and expanded to enable the flexible and scalable manufacture of a broad range of APIs. Current efforts are focused on addressing regulatory approval requirements and expanding the capability to enable production of critical medicines and precursors needed to treat critical care COVID-19 patients.

Make-It performers are building a suite of flexible manufacturing capabilities for scalable, resilient production of important medicines:

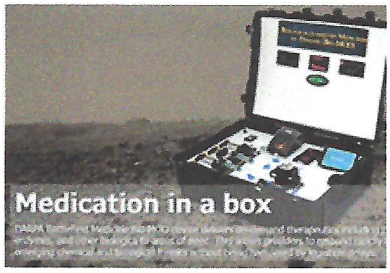
- On Demand Pharmaceuticals' (ODP) focus is on the production of fine chemical reagents and active pharmaceutical ingredients (APIs), and their technology is based on small-footprint chemical manufacturing devices that were developed in DARPA's Battlefield Medicine and Make-It programs. Their effort is jointly funded by DARPA and HHS under the CARES Act, and the company enjoyed a visit from FDA Commissioner, Dr. Stephen Hahn, as well as DARPA's Deputy Director, Dr. Peter Highnam, on 3 December.
- SRI International is developing an approach that enables simple scaling of flow-based pharmaceutical production from bench-top to production scale in a single step.
- Virginia Commonwealth University is building tools to analyze and optimize U.S. based chemical manufacturing to enable rapid reallocation of existing on-shore process streams to critical APIs in a time of need.

For more information on the highlighted programs, we invite you to visit the appropriate program page. In addition, please continue to follow this space for timely updates on DARPA's efforts

IMAGES



Abott ID NOW Point of Care Test



Bio-MOD Delivers On-Demand Therapeutics

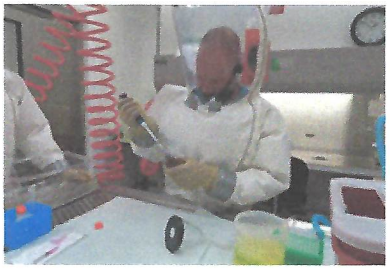
Plant-based vaccine production

First Trials for Moderna Antibody-based Vaccine

DARPA Researcher at NY Icahn School of Medicine Mt. Sinai Medical Center Testing C-19 Samples

UNMC Researchers Reference Testing on PCR

DARPA Researcher Stephanie Seifert at RML Investigating Zoonotic Diseases

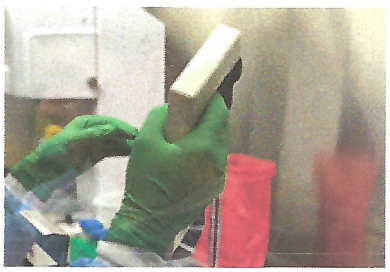


DARPA Researcher Vincent Munster at RML Developing Challenge Models for Novel Viruses

DARPA Researcher Yinda Kwe Claude at RML

DARPA Researchers at Vanderbilt Investigating C-19 Antibodies

DARPA Researchers at Vanderbilt Working on Antibody Discovery



DARPA Researchers at Vanderbilt Working on Antibody Discovery 2

UNMC Researcher Suiting to Collect Samples from C-19 Patient

TAGS

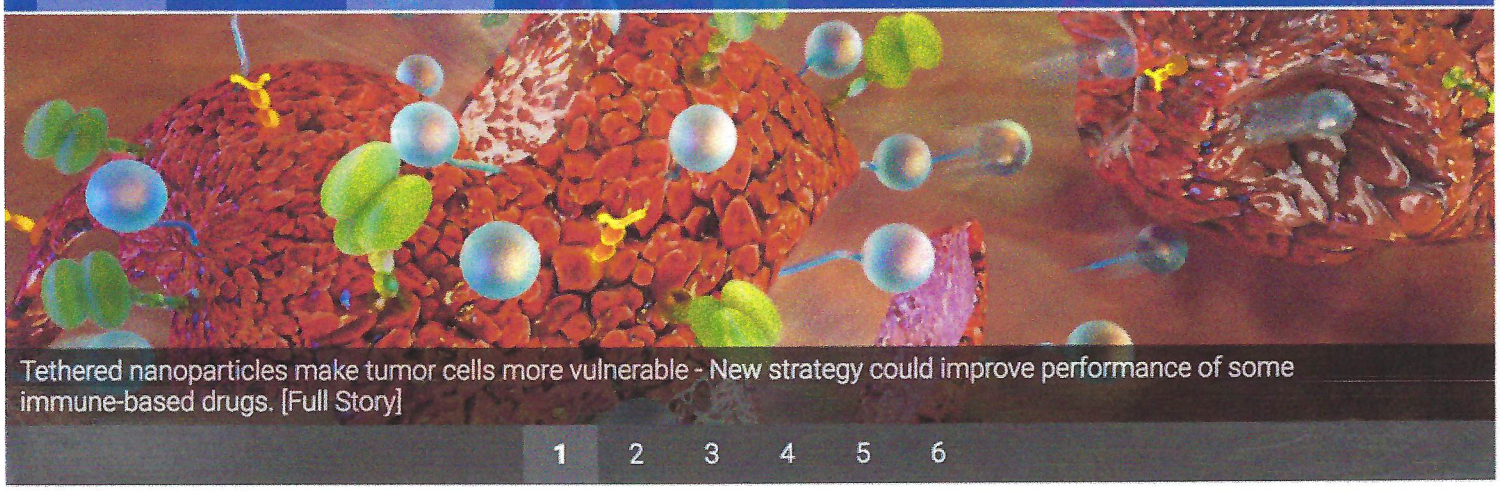
| Administration | Agency | COVID-19 | Health | Leadership |

SIMILARLY TAGGED CONTENT

Covid 19 Press Coverage
Dr. Peter Highnam
Stefanie Tompkins Appointed 23rd DARPA Director
Victoria Coleman Sworn In as 22nd DARPA Director
Acting Dir. Highnam Discusses COVID-19

Langer Lab

MIT Department of Chemical Engineering



Tethered nanoparticles make tumor cells more vulnerable - New strategy could improve performance of some immune-based drugs. [Full Story]

1 2 3 4 5 6

Research Overview

Our work is at the interface of biotechnology and materials science. A major focus is the study and development of polymers to deliver drugs, particularly genetically engineered proteins, DNA and RNAi, continuously at controlled rates for prolonged periods of time. Work is in progress in the following areas.

- Investigating the mechanism of release from polymeric delivery systems with concomitant microstructural analysis and mathematical modeling
- Studying applications of these systems including the development of effective long-term delivery systems for insulin, anti-cancer drugs, growth factors, gene therapy agents and vaccines
- Developing controlled release systems that can be magnetically, ultrasonically, or enzymatically triggered to increase release rates

More on Lab Research >>

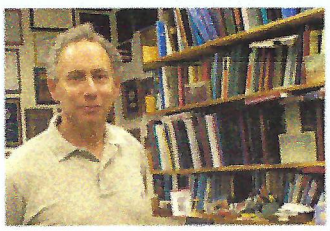
NEWS & EVENTS

Bob Langer receives the 2020 Maurice Marie-Janot Award

The 15th US-Japan Symposium on Drug Delivery Systems Conference was held in Hawaii in December 2019

Robert Langer wins the 2019 Dreyfus Prize in Chemical Sciences

[More News]



Robert S. Langer
David H. Koch (1962) Institute

MAILING ADDRESS

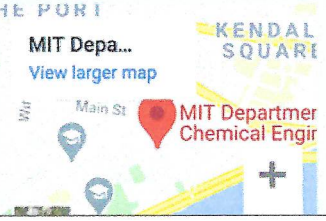
Langer Lab
Massachusetts Institute of Techonology
77 Massachusetts Avenue
Room 76-661
Cambridge, MA 02139-4307

GENERAL INQUIRIES

Phone: 617.253.3123
Fax: 617.258.8827
Accessibility

EXHIBIT 4

MAP & DIRECTION TO OUR LAB



Research

Work is in progress in the following areas:

- Investigating the mechanism of release from polymeric delivery systems with concomitant microstructural analysis and mathematical modeling
- Studying applications of these systems including the development of effective long-term delivery systems for insulin, anti-cancer drugs, growth factors, gene therapy agents and vaccines
- Developing controlled release systems that can be magnetically, ultrasonically, or enzymatically triggered to increase release rates
- Synthesizing new biodegradable polymeric delivery systems which will ultimately be absorbed by the body
- Creating new approaches for delivering drugs such as proteins and genes across complex barriers in the body such as the blood-brain barrier, the intestine, the lung and the skin
- Researching new ways to create tissue and organs including creating new polymer systems for tissue engineering
- Stem cell research including controlling growth and differentiation
- Creating new biomaterials with shape memory or surface switching properties
- Angiogenesis inhibition

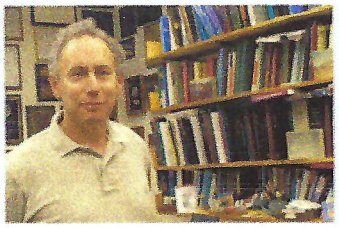
NEWS & EVENTS

Bob Langer receives the 2020 Maurice Marie-Janot Award

The 15th US-Japan Symposium on Drug Delivery Systems Conference was held in Hawaii in December 2019

Robert Langer wins the 2019 Dreyfus Prize in Chemical Sciences

[**More News**]



Robert S. Langer
David H. Koch (1962) Institute Professor

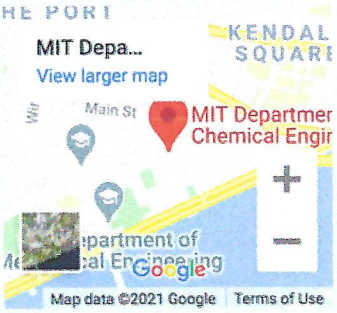
MAILING ADDRESS

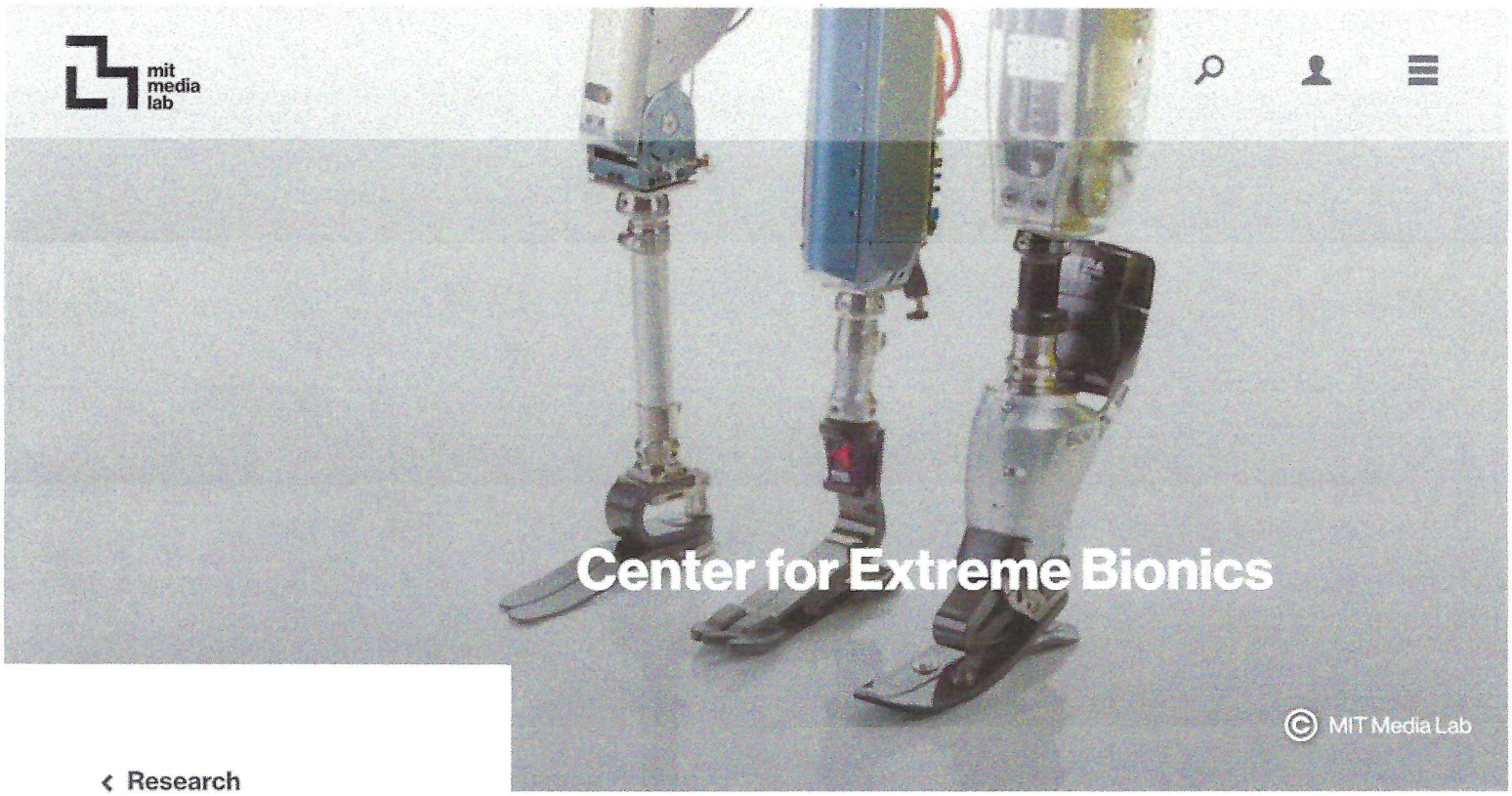
Langer Lab
Massachusetts Institute of Techonology
77 Massachusetts Avenue
Room 76-661
Cambridge, MA 02139-4307

GENERAL INQUIRIES

Phone: 617.253.3123
Fax: 617.258.8827
Accessibility

MAP & DIRECTION TO OUR LAB





Center for Extreme Bionics

‹ Research

In this Group:

Overview

Updates

People

Projects

Publications

Half of the world's population currently suffers from some form of physical or neurological disability. At some point in our lives, it is all too likely that a family member or friend will be struck by a limiting or incapacitating condition, from dementia, to the loss of a limb, to a debilitating disease such as Parkinson's. Today we acknowledge—and even "accept"—serious physical and mental impairments as inherent to the human condition. But must these conditions be accepted as "normal"? What if, instead, through the invention and deployment of novel technologies, we could control biological processes within the body in order to repair or even eradicate them? What if there were no such thing as human disability?

These questions drive the work of faculty members Hugh Herr, Ed Boyden, Canan Dagdeviren, Joe Jacobson, Deblina Sarkar, and Institute Professor Robert Langer, and has led them and the MIT Media Lab to establish the Center for Extreme Bionics. This dynamic new interdisciplinary organization draws on the existing strengths of research in synthetic neurobiology, biomechatronics, and biomaterials, combined with enhanced capabilities for design development and prototyping.