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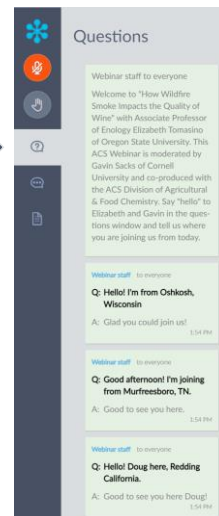
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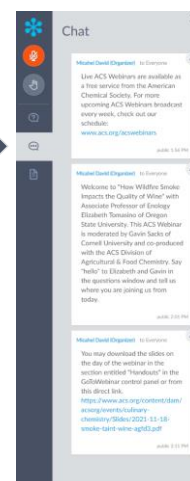
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Announcements and hyperlinks from our team



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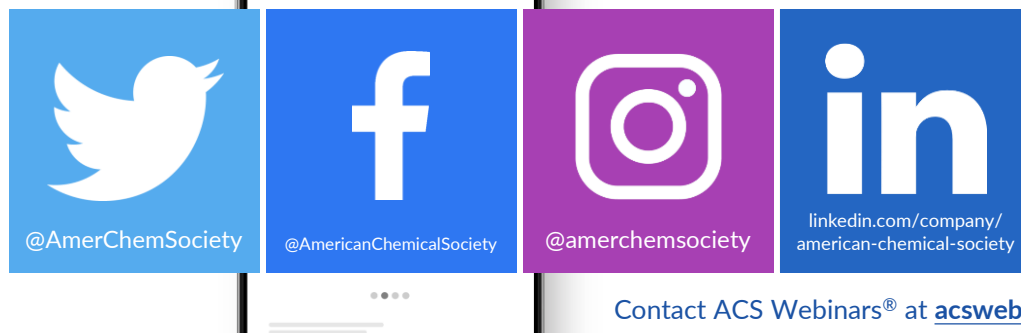


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## A Career Planning Tool For Chemical Scientists



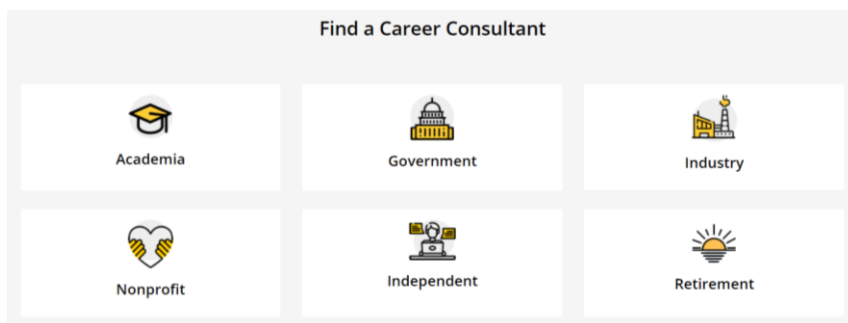
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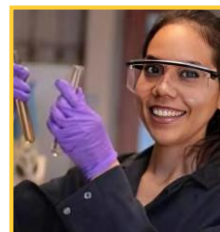


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### ACS Scholar Adunoluwa Obisesan

BS, Massachusetts Institute of Technology, June 2021  
(Chemical-biological Engineering, Computer Science & Molecular Biology)

*"The ACS Scholars Program provided me with monetary support as well as a valuable network of peers and mentors who have transformed my life and will help me in my future endeavors. The program enabled me to achieve more than I could have ever dreamed. Thank you so much!"*

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# ACS OFFICE OF DEIR

Advancing ACS' Core Value of Diversity, Equity, Inclusion and Respect



## Resources

<b>Inclusivity Style Guide</b> Designed to help staff and members use language and images that respect diversity in all its forms. →	<b>ACS Webinars on Diversity</b> Covering diversity and inclusion at the workplace →
<b>ACS Publications DEIR Hub</b> See what ACS Publications is doing for fostering inclusivity in scholarly publishing →	<b>ACS Volunteer and ACS Meetings Code of Conduct</b> Fostering a positive and welcoming environment for attendees, volunteers and staff. →
<b>C&amp;EN Trailblazers</b> C&EN highlights scientists from different backgrounds who are making an impact in chemistry. →	<b>NEW! Download DEIR Educational Resources</b> Download this educational guide for additional recommendations on videos, articles, books, podcasts, and more on diversity, inclusion, and related topics. →
<b>Quick Guide: Inclusion Moments</b> Learn more about what Inclusion Moments are and see ideas to host them during your meetings. →	<b>Quick Guide: How to host inclusive in-person events</b> Recommendations and best practices to ensure that your events can accommodate everyone. →

## Diversity, Equity, Inclusion, and Respect

\*\*Adapted from definitions from the Ford Foundation Center for Social Justice:

### Equity\*\*

Seeks to ensure fair treatment, equality of opportunity, and fairness in access to information and resources for all. We believe this is only possible in an environment built on respect and dignity. Equity requires the identification and elimination of barriers that have prevented the full participation of some groups.

### Diversity\*\*

The representation of varied identities and differences (race, ethnicity, gender, disability, sexual orientation, gender identity, national origin, tribe, caste, socioeconomic status, thinking and communication styles, etc.) collectively and as individuals. ACS seeks to proactively engage, understand, and draw on a variety of perspectives.

### Inclusion\*\*

Builds a culture of belonging by actively inviting the contribution and participation of all people. Every person's voice adds value, and ACS strives to create balance in the face of power differences. In addition, no one person can or should be called upon to represent an entire community.

### Respect

Ensures that each person is treated with professionalism, integrity, and ethics underpinning all interpersonal interactions.

<https://www.acs.org/diversity>

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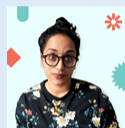
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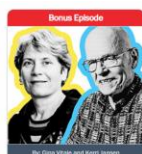
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**Bonus Episode**  
Carolyn Bertozzi and K. Barry Sharpless chat about sharing the 2022 Nobel Prize in Chemistry  
December 6, 2022



**Bonus Episode**  
Bioorthogonal, click chemistry clinch the Nobel Prize  
October 5, 2022



**Episode #46**  
Lithium mining's water use sparks bitter conflicts and novel chemistry  
September 13, 2022



**Bonus Episode**  
Happy 100th birthday, John Goodenough!  
For John Goodenough's 100th birthday, Stereo Chemistry revisits a fan-favorite interview with the renowned scientist  
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**Bonus Episode**  
Jesse Wade on Wikipedia and work-life balance  
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**Bonus Episode**  
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## ACS Career Resources



### Virtual Office Hours



<https://www.acs.org/careerconsulting.html>

### Personal Career Consultations

**Jim Tung**

Assistant  
Lacamas Laboratories

S.S., Biochemistry, University of Oregon  
Ph.D., Organic Chemistry, University of Notre Dame

Jim Tung works at Lacamas Laboratories in Portland, OR, currently as a business development manager. He has been with Lacamas for 10 years, working on developing new chemical manufacturing projects. Before that, he was a senior research chemist at Orlite Research in Champaign, IL, performing kilo-scale organic chemistry.

An Oregon native, Jim got his B.S. in biochemistry from the University of Oregon, his Ph.D. in organic chemistry from the University of Notre Dame, with postdoctoral experience at Pfizer's laboratories in La Jolla, CA. He is past chair of the Portland Section of the American Chemical Society and was 2019 general co-chair of NORM 2019. He has interests in process chemistry, labor economics, social media outreach and encouraging career exploration and development for younger chemists.

**Ask me about:**

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- Applying for academic jobs
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Contact With Jim

<https://www.acs.org/careerconsulting.html>

### LinkedIn Learning



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Thursday, September 7, 2023 | 2-3pm ET

### Mentors, Imposter Syndrome, and Diversity

Co-produced with ACS Office of Diversity, Equity, Inclusion, and Respect



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## Plant-Cell Based Drug Delivery: Enhancing Affordability and Access to Healthcare



**HENRY DANIELL, PhD**

W. D. Miller Professor & Vice Chair, Department of  
Basic and Translational Sciences, School of Dental  
Medicine, University of Pennsylvania



**CHRISTA E. MÜLLER, PhD**

Head of Department, Pharmaceutical Institute,  
University of Bonn, Germany, and Editor-in-Chief,  
*ACS Pharmacology & Translational Science*

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## Plant Cell Based Drug Delivery: Enhancing Affordability and Access to Healthcare



### Dr. Henry Daniell

W. D. Miller Professor  
Director of Translational Research  
Vice Chair, Department of Basic and Translational Sciences

School of Dental Medicine  
University of Pennsylvania, Philadelphia, USA

Founding Editor, Editor in Chief, Editor Emeritus  
*Plant Biotechnology Journal*, Oxford, UK

[hdaniell@upenn.edu](mailto:hdaniell@upenn.edu)

[www.dental.upenn.edu/hdaniell](http://www.dental.upenn.edu/hdaniell)

<http://scholar.google.com/citations?user=7sow4jwAAAAJ&hl=en>

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## FDA approves \$3.5 million treatment for hemophilia, now the most expensive drug in the world

By Deldre McPhillips, CNN  
Published 4:26 PM EST, Wed November 23, 2022



FDA approved Hemgenix based on safety and effectiveness evaluated in two studies of about 60 adult men.

**Single gene therapy treatment for Hemophilia A is \$2.9 million; for hemophilia B is \$3.5 million**

**New \$2.9 Million Gene Therapy Promises to Remake Hemophilia Treatment**  
*BioMarin's gene therapy is the first to win FDA approval for adults with the most common form of the bleeding disorder*

By [Jared S. Hopkins](#) - June 29, 2023 5:31 pm ET **Wall Street Journal**



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## Diabetes is a Silent Epidemic, but Treatment is Expensive

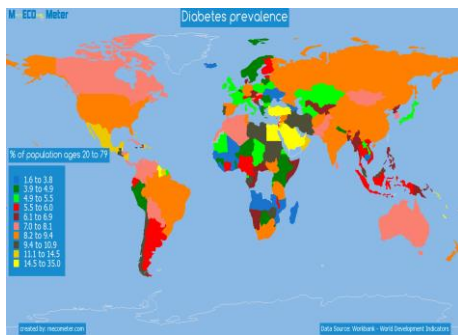
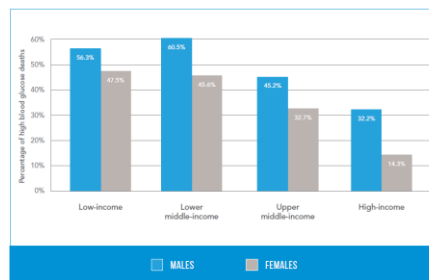


FIGURE 2. PERCENTAGE OF DEATHS ATTRIBUTED TO HIGH BLOOD GLUCOSE THAT OCCUR AT AGES 20-69 YEARS, BY SEX AND COUNTRY INCOME GROUP, 2012



- 536 million adults live with diagnosed diabetes – many not diagnosed
- Diabetes caused 6.7 million deaths in 2021 (COVID 1.1 million 2020-2023, US)
- Insulin pump costs \$6000-\$12,000; 1/3<sup>rd</sup> of global population earn \$2/day
- Insulin market size is \$20.35 billion in 2021
- Insulin cost doubled in the US in five years
- Annual sales of top ten protein drugs (\$200 billion), exceeds 3/4<sup>th</sup> global GDP
- Medicare beneficiaries out of pocket costs for insulin was >\$1 billion in 2020 but was \$236 million in 2007.
- So, American diabetics risk their lives by reducing their insulin dose !!



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**Current protein drug delivery systems – >90% invasive**



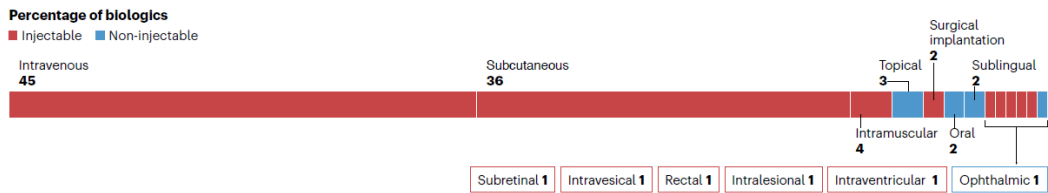
**Oral or topical protein drug delivery systems - noninvasive**



FDA approved protein drugs: Oral Arah bioencapsulated in peanut cells to treat allergy; Topical ACE2 bioencapsulated in lettuce to debulk SARS-CoV-2 infection/transmission in phase I/II human clinical trial

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**Fig. 1 | FDA-approved biologic drug delivery methods and percentage of each method since 2015.** Data are from the Center for Biologics Evaluation and Research (Biological Approvals by Year) and Center for Drug Evaluation and Research (Purple Book) database through December 2022. The FDA has approved 89 protein drugs since 2015, excluding monoclonal antibodies and vaccines. Red indicates that an injection is required for that delivery method.

nature biotechnology

<https://doi.org/10.1038/s41587-023-01899-1>

# Plant cell-based drug delivery enhances affordability of biologics

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## Why are Biopharmaceuticals Expensive?

*Current system* vs *New system*



**Fermentation**



**Purification**



### **Oral Delivery of plant cells with protein drugs**

- \$500-900 million cost of fermenters
- Prohibitively expensive purification
- Invasive delivery – injections/implantation
- Refrigeration/freezing required
- Short shelf-life
- Average development cost \$2.6 billion
- New protein drugs cost 18,861- \$288,759

No need for fermenters – produced in greenhouses  
 FDA approved drugs without purification  
 Oral/topical delivery – non-invasive  
 No need for cold chain  
 Stable at ambient temp for many years  
 Much less (\$10 M topical -\$25 million oral drug)  
 Oral Palforzia \$2,500 (<3% of new biologic drug)

\*VaxGen Published Information

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## It is the drug delivery technology - stupid

- When I moved to the US 40 years ago, my first operated assisted phone call cost \$75 (10% of my salary) – 45 days to get a response to mailed letters
- Today, WhatsApp, Zoom, Skype – instant and cheap
- Insulin was delivered by injections fifty years ago and still today
- >95% of drugs approved by FDA are injected.
- Injections are not suitable for drug delivery, especially for diabetes
- Injections rapidly decrease sugar levels leading to hypoglycemia
- Insulin delivery to the peripheral circulation by injections is a major reason for hypoglycemia – natural insulin is secreted by the pancreas

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**Plant selection with inserted gene**

**Hydroponic system**

**Freeze dryer**

**Freeze-dried leaves**

**Ground powder**

**Capsules**

**Gum tablets**

Daniell et al - Ann Rev Genetics 50: 595, 2017; Daniell et al - Genome Biology 17: 134, 2016

Daniell et al – Plant Biotechnology Journal 19: 430-447, 2021

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## Large Scale Protein Drug Production Facilities

### University of Pennsylvania – Daniell lab greenhouse



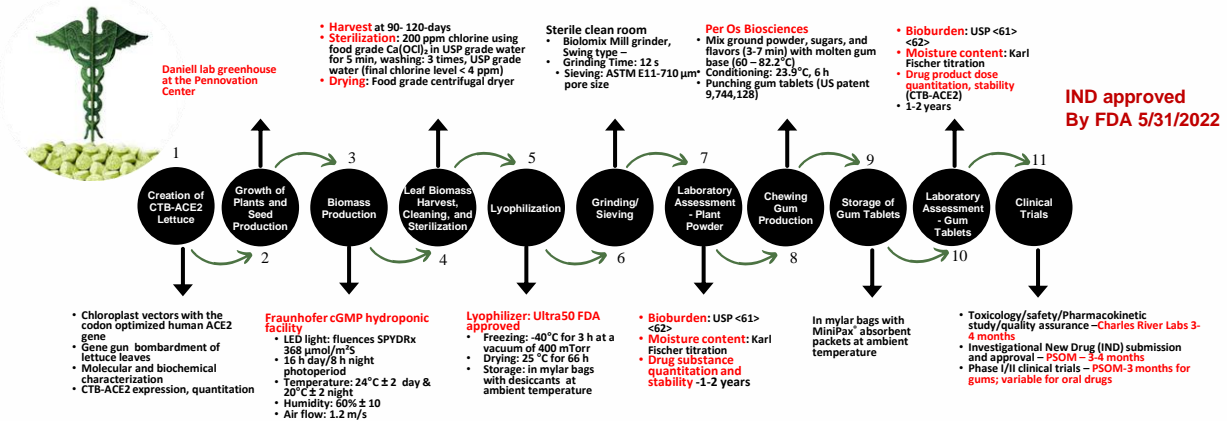
Although indoor hydroponic facility has been used in the past, Greenhouse produced leaf biomass meets FDA requirements for drug dose, stability, uniformity and bioburden.

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## From Lab to the Clinic – CTB-ACE2 chewing gum



### Products ready for advancing to clinical trials – in step 11:

- **ACE2 gum** to reduce SARS-CoV-2 infection/transmission – IND approved by FDA – Phase I/II studies in progress – Phase III in 2023
- **FRIL gum** to reduce SARS-CoV-2, Influenza, HSV, RSV infection/transmission – IND to be filed for Phase I/II studies in 2023
- **Dextranase/mutanase/lipase gum** to kill bacterial/fungi in dental plaque – IND to be filed for Phase I/II studies in 2023
- **Oral ACE2/Ang1-7** for cardiopulmonary diseases – **Rat/dog efficacy/tox done** - Revised IND to be filed for Phase I/II studies in 2023
- **Oral insulin – animal studies completed- canine insulin trial initiated** - IND to be filed for Phase I/II studies in 2023
- **Oral insulin like growth factor – acceleration of diabetic fracture healing - animal studies completed** – IND to be filed in 2023
- **Oral COVID-19 booster vaccine – animal studies not yet completed** - IND to be filed in 2023

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### FDA approval of ACE2 chewing Gum to prevent SARS-CoV-2 Infection/transmission

- First engineered clinical product (human protein) made in plant cells via the chloroplast genome
- First clinical product without need for purification or cold chain – ACE2 stability at ambient temperature for many years
- Scale up - a million ACE2 gum tablets made from one kilogram of dry leaf powder
- CTB approved with ACEs – Enables oral drug delivery including CTB-insulin

From: Do, Ngoc-Linh <[Ngoc-Linh.Do@fda.hhs.gov](mailto:Ngoc-Linh.Do@fda.hhs.gov)>

Sent: Tuesday, May 31, 2022 3:03 PM

To: Blatcher, David <[David.Blatcher@pennmedicine.upenn.edu](mailto:David.Blatcher@pennmedicine.upenn.edu)>

Subject: [External] IND 154807 ACE2 Chewing Gum

Dear David,

We have completed our review of IND 154807 and have concluded that you may proceed with your proposed study. We will issue a study may proceed letter within 30 days with non-hold comments for your considerations.

Thank you,

Lin

*Ngoc-Linh Do, PharmD*

*Regulatory Health Project Manager*

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Test	Specification	4 weeks (±7 days) Estimated	12 weeks (±7 days)	26 weeks (±14 days)	52 weeks (±14 days)
Date:	Estimated	12-May-2022	7-July-2022	13-Oct-2022	14-Apr-2023
	Actual	25-May-2022	28-July-2022	10-Oct-2022	
Description	light to dark green tablets: Diameter: 0.65" (16.4mm) Thickness: 0.33" (8.3mm)	Pass	Pass	Pass	
Microbial Limits (Bioburden)	Total aerobic microbial count 10 <sup>3</sup> cfu/g	0	0	0	
	Total yeast 10 <sup>3</sup> cfu/g	0	0	0	
	Total molds 10 <sup>4</sup> cfu/g	0	0	0	
	Absence of Salmonella	Absent	Absent	Absent	
	Absence of Escherichia coli	Absent	Absent	Absent	
Drug dosage	250-1,000 µg ACE2 per 2g dry weight of gum tablet	752.6 ±3.4 µg	755 ± 3.1 µg	755.9 ± 2.3 µg	
Potency	80% - 110% virus serum neutralization	100%*	NA	100%	

## ACE2 gum FDA evaluation criteria before and after IND approval

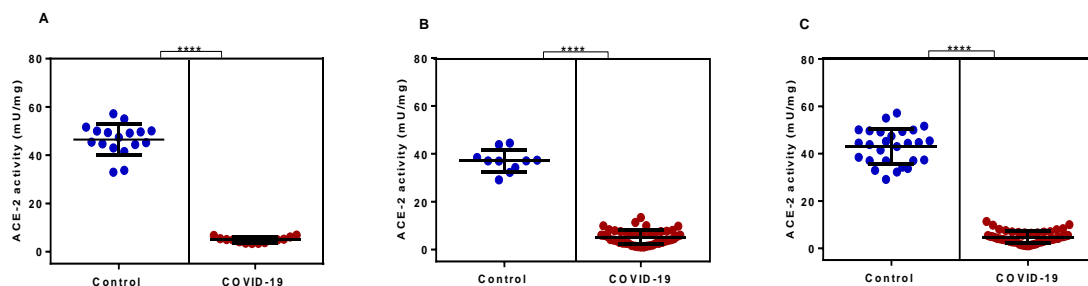
- All pipettes, equipment, should be calibrated and certified
- All reagent safety data and batch record should be filed
- All assays should be calibrated and certified
- All data should be performed by more than one investigator and supervisor certified
- FDA should have access for verification of data
- All project personnel should be certified for performing cGMP investigations and documentation.
- No data should be discarded, including failed or incomplete experiments

Daniell lab facilities at the University of Pennsylvania and investigators meet FDA requirements for cGMP product development, characterization and documentation – equipment calibration, training certification, etc.

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## What happens to COVID-19 patients after SARS-CoV-2 infection Plasma ACE2 enzyme activity in control and COVID-19 patients

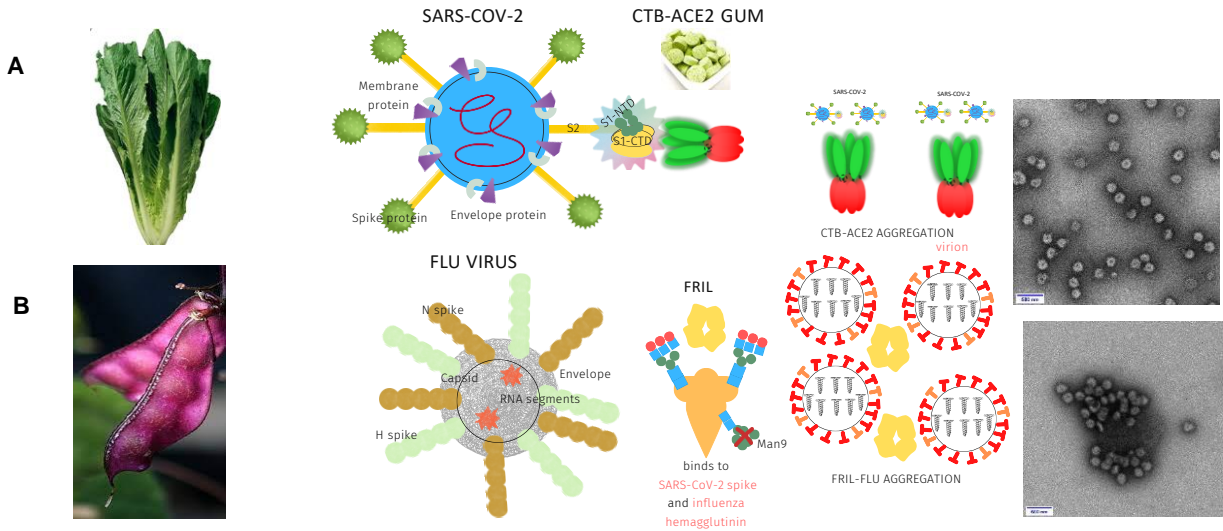


ACE2 activity determined by cleavage of fluorogenic McaAPK (Dnp) substrate. ACE2 enzyme activity units (mU/mg) calculated in Control and COVID-19 patients. **(A)** In EDTA treated 17 control (blue) and 16 COVID-19 (red) samples **(B)** In Non-EDTA treated 10 control (blue) and 43 COVID-19 (red) samples. **(C)** Both EDTA and Non EDTA samples combined data. Data were analyzed using the Mann-Whitney U Test; \*\*\*\*:  $p < 0.0001$ .

**Daniell et al Molecular Therapy – Methods and Clinical Development 26: 266, September 2022**

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**Blocking and neutralization mechanisms of plant-based SARS-CoV-2 viral trap proteins - CTB-ACE2 and FRIL**

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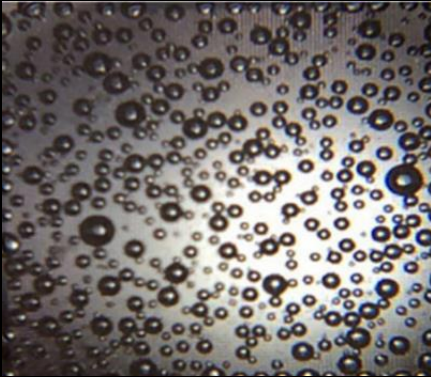
Bubble = Virus

<https://doi.org/10.1016/j.ymthe.2021.11.008>

Before Treatment  
with Covid Gum

After Treatment  
with Covid Gum

COVID-19  
Swab Samples

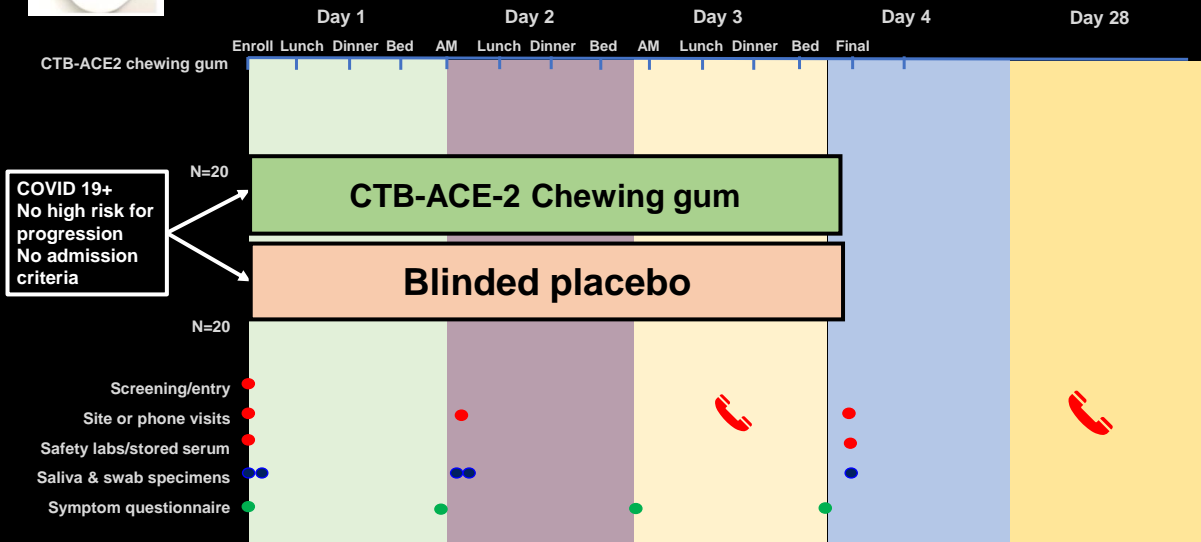


Results above is observed with one ug of CTB-ACE2 but each gum contains ~750 ug CTB-ACE2  
Daniell et al Molecular Therapy 30: 1966-1978, 2022; Biomaterials 288: 121671, 2022

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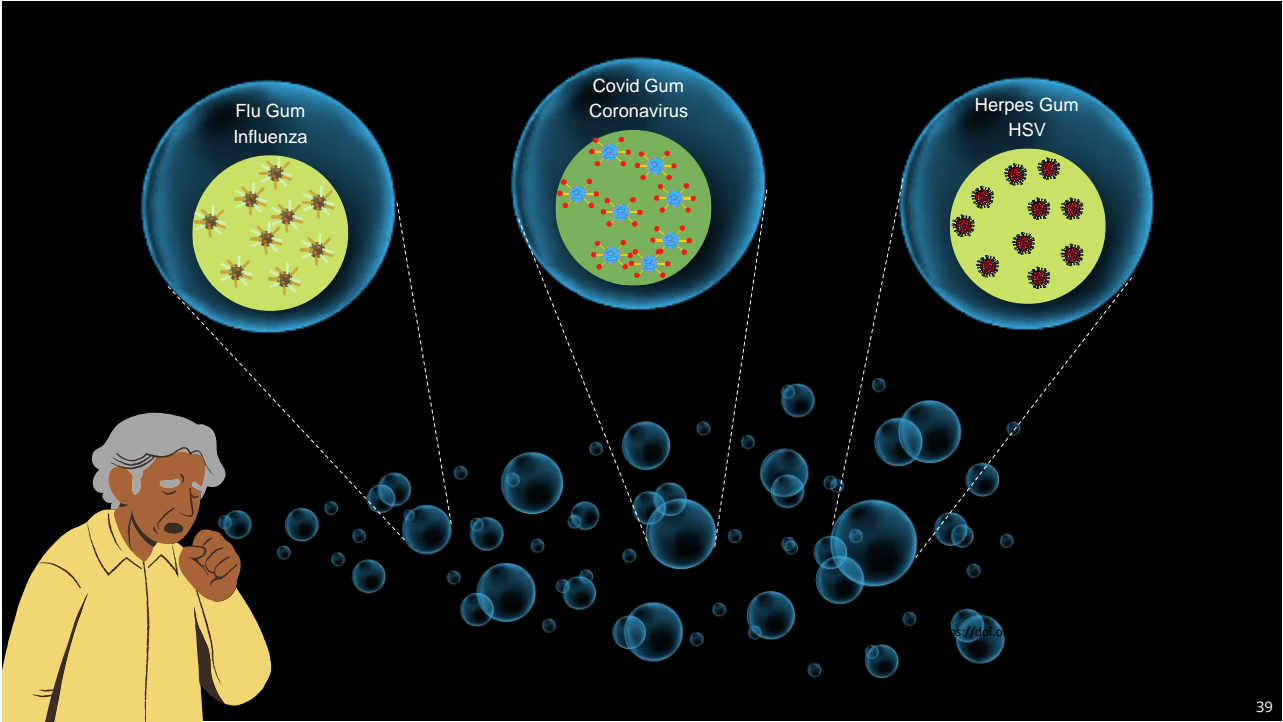
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## FDA approved IND: CTB-ACE2 chewing gum IND 154807, NCT05433181



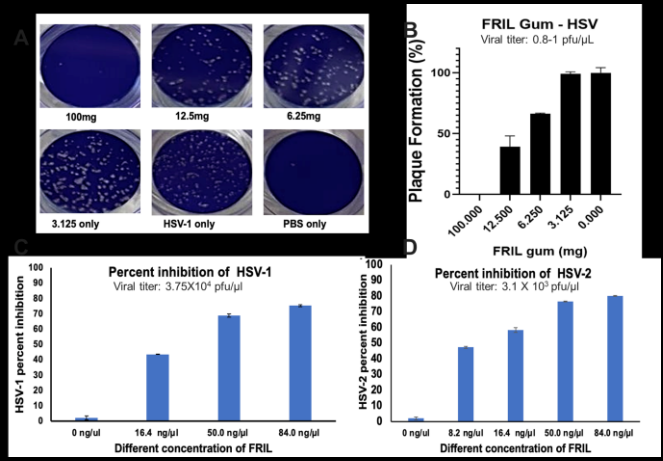
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**Neutralization of HSV-1, HSV-2, H1N1 by FRIL gum – Plaque reduction assay or ELISA**



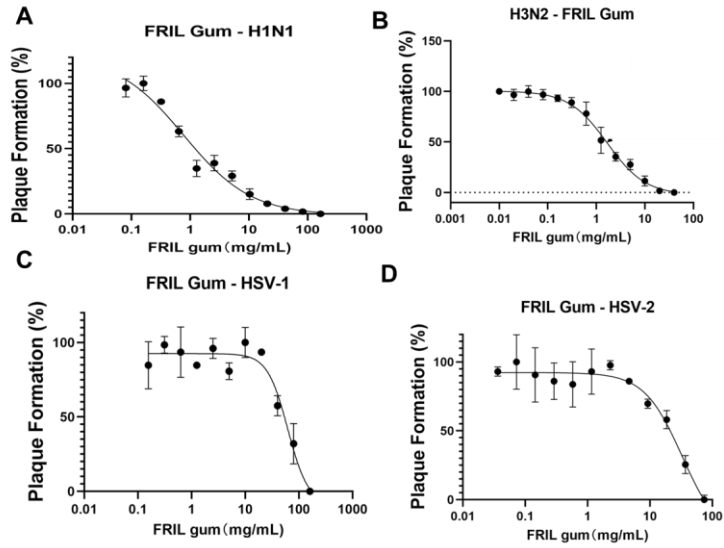
**Each chewing gum contains ~1,800 ug FRIL – to neutralize >1,000 viruses, only small quantity FRIL is required.**

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## Virus neutralization by FRIL Gum



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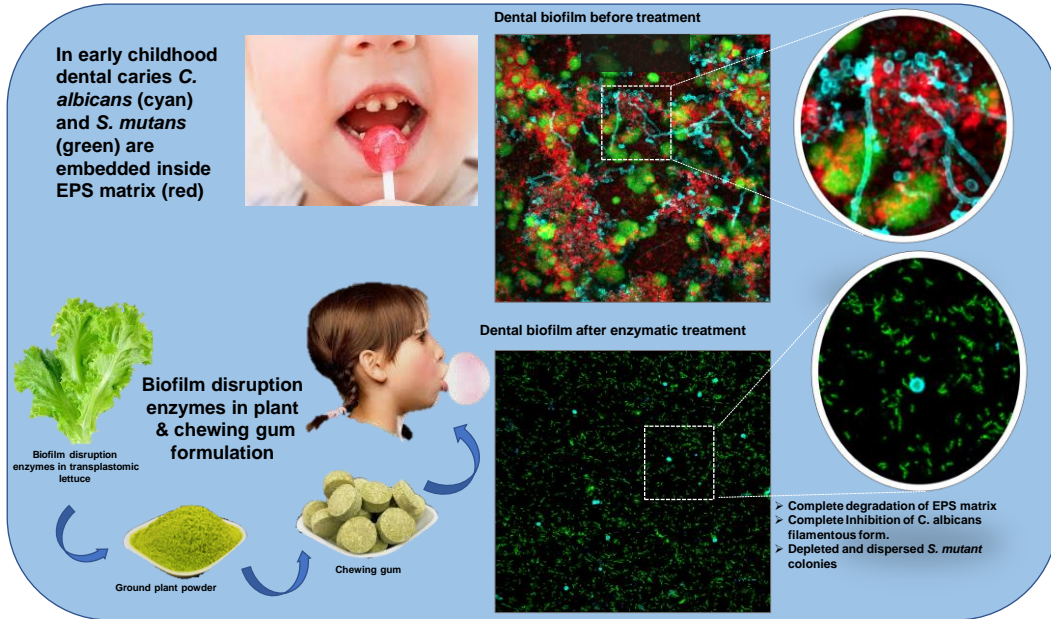
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## Plaque removal by chewing gums Mechanical vs Biological



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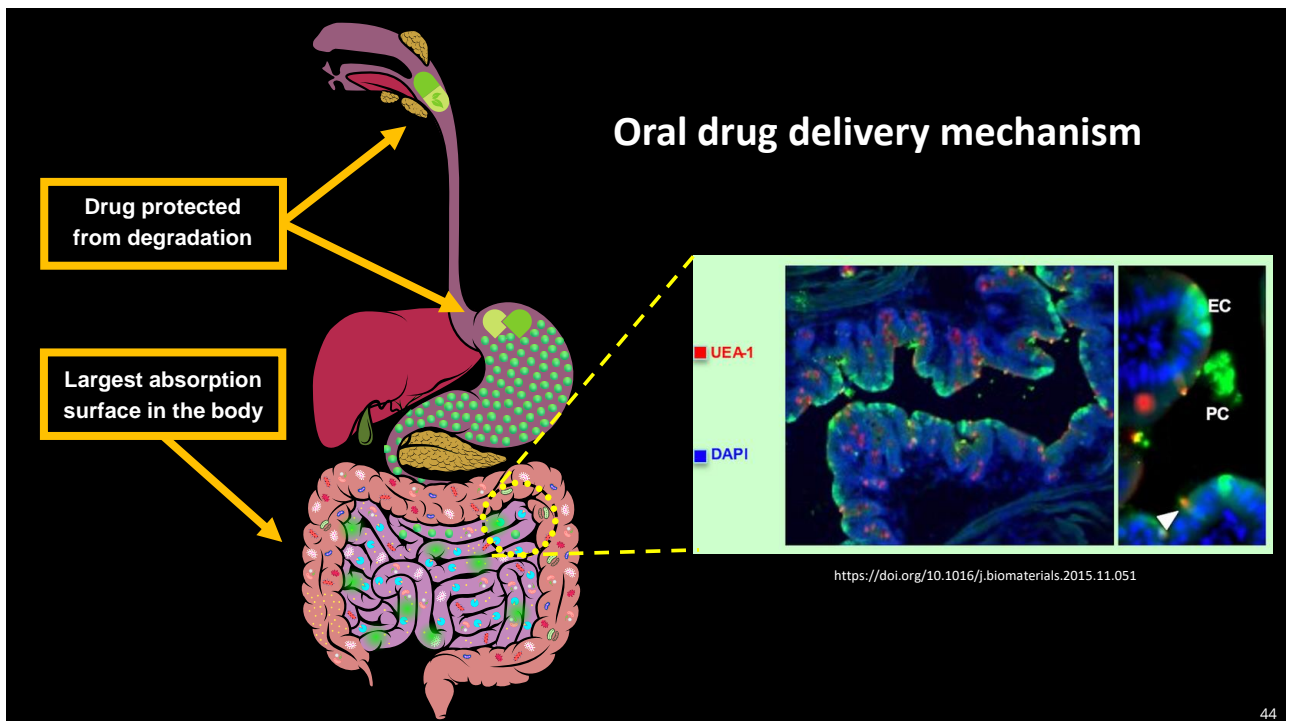
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Singh et al., *Plant Biotechnology Journal*, 19, 2113-2125.

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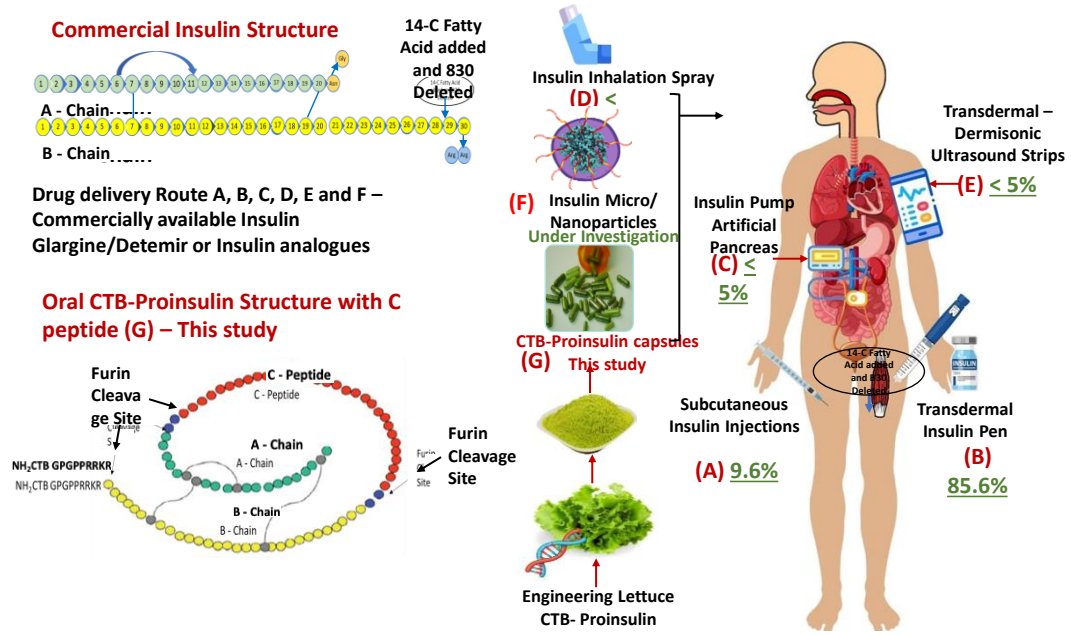
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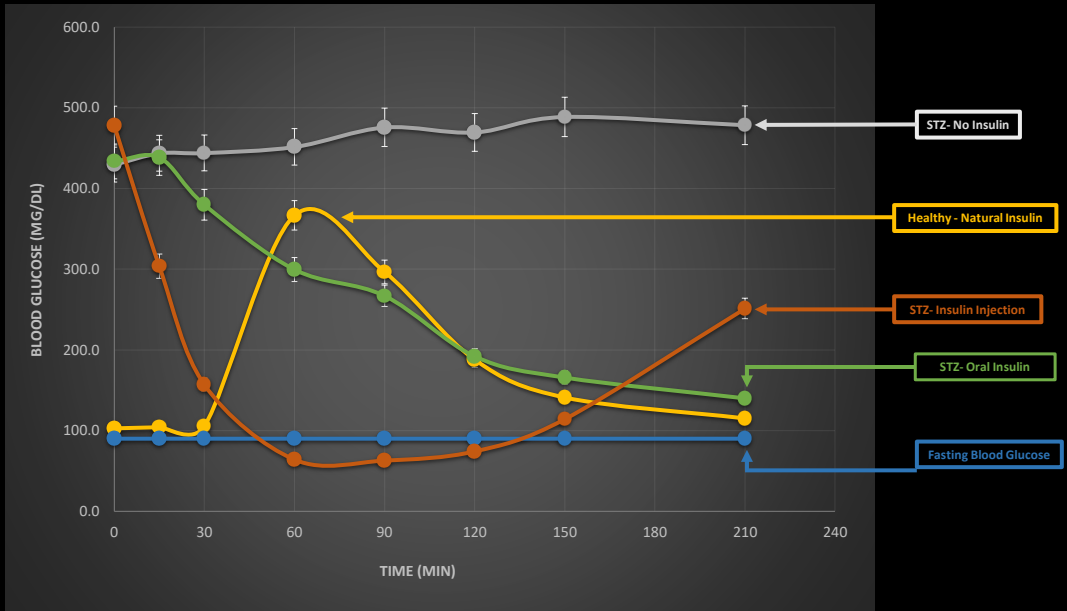


Daniell et al Biomaterials – June 2023 – 298: 122142

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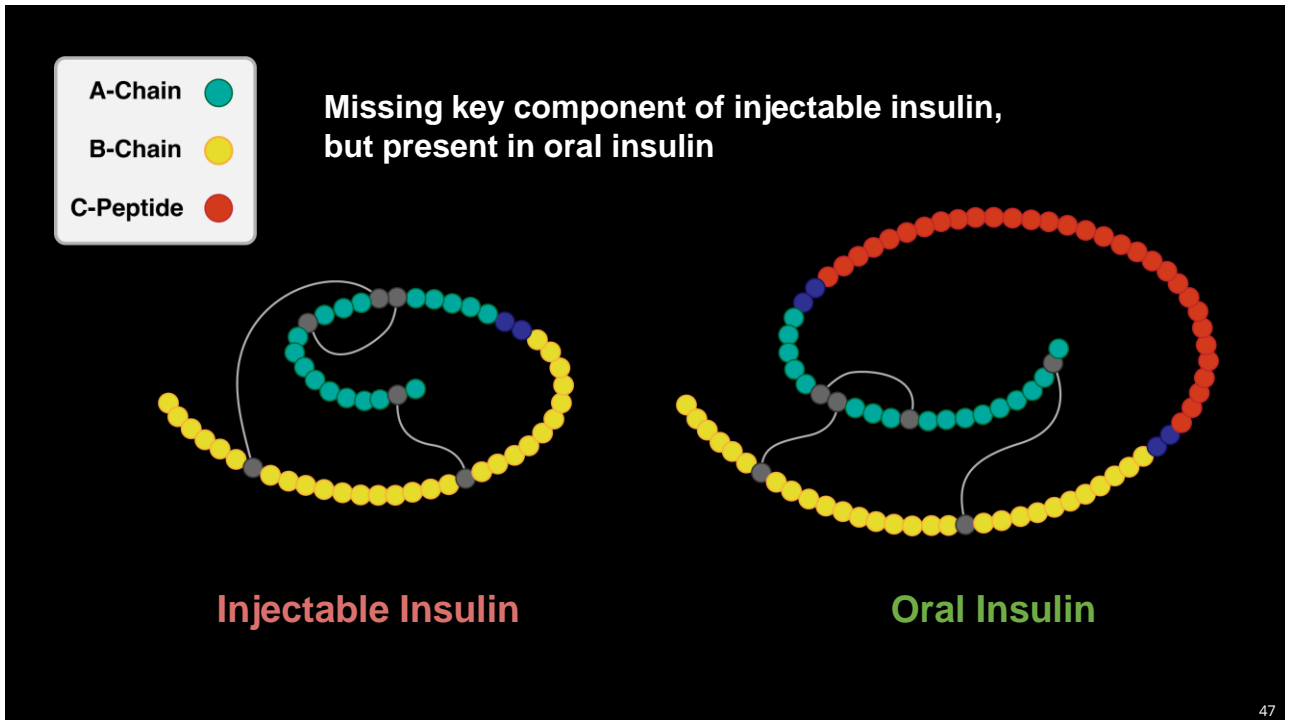
**Oral versus injectable insulin - Dr. Singh poster # 18456**



Daniell et al Biomaterials – June 2023 – 298: 122142

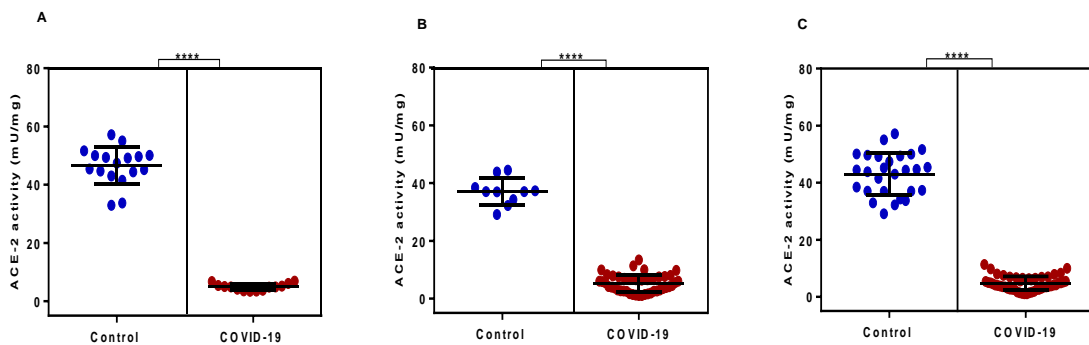
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## What happens to COVID-19 patients after SARS-CoV-2 infection Plasma ACE2 enzyme activity in control and COVID-19 patients

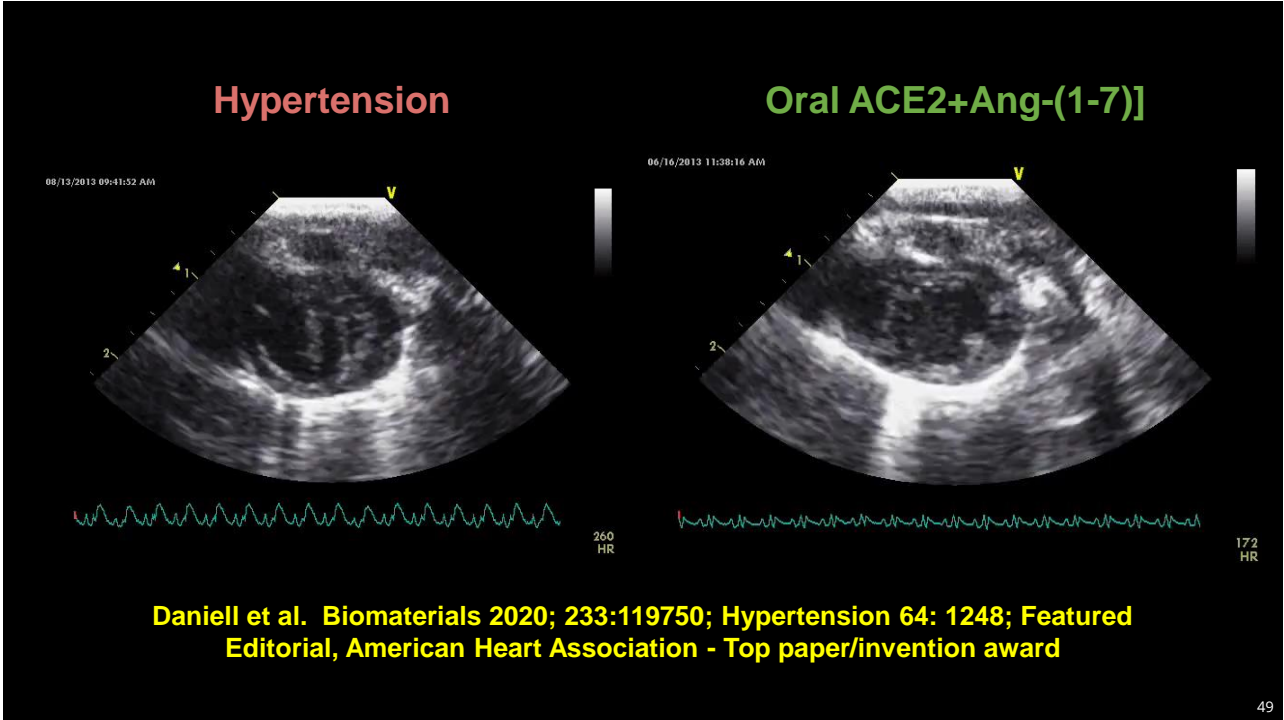


ACE2 activity determined by cleavage of fluorogenic McaAPK (Dnp) substrate. ACE2 enzyme activity units (mU/mg) calculated in Control and COVID-19 patients. **(A)** In EDTA treated 17 control (blue) and 16 COVID-19 (red) samples **(B)** In Non-EDTA treated 10 control (blue) and 43 COVID-19 (red) samples. **(C)** Both EDTA and Non EDTA samples combined data. Data were analyzed using the Mann-Whitney U Test; \*\*\*\*:  $p < 0.0001$ .

**Daniell et al Molecular Therapy – Methods and Clinical Development 26: 266, September 2022**

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Development

~~\$2.6 billion~~

\$10-\$25 million

50

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Production

\$0

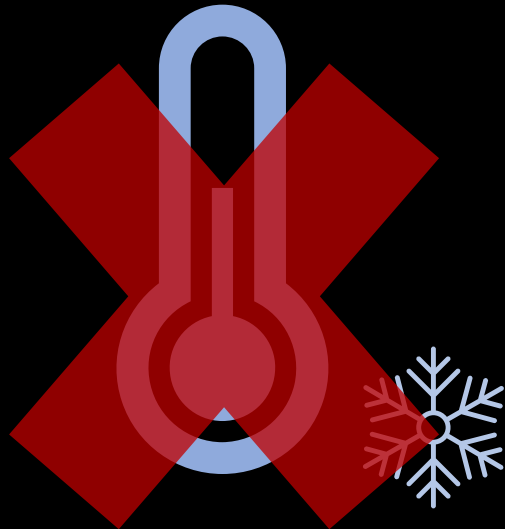


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Storage



**Last year, 19 million donated COVID-19 vaccines were destroyed in Africa due to lack of freezers**

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**10x - 50x cheaper**  
than traditional drugs

**In order to enhance access to global health and affordability,  
technology revolution is needed.  
Plant produced biopharmaceuticals offers such an opportunity.**

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## Research Funding

**NIH – GMS/HL: R01** – 2002-2025: Oral delivery of affordable protein drugs  
**NIH- HL: R01** 2011-2022: Oral therapy for hemophilia – tolerance induction  
**Pennsylvania Governors office** - 2020 IND gap studies identified by FDA after filing regulatory documents  
**IDEA award** – CiPD and Penn HealthTech  
**NIH – EY: R01**- 2015-2020: Diabetic retinopathy – Oral ACE2/Ang1-7  
**NIH – SMARTT** - 2016-2020: Hemophilia IND filing/phase I  
**NIH – SMARTT** - 2016-2020: Hypertension IND filing/phase I  
**DOE**: 2012- 2020 PETRO plants, Synplastome  
**Takeda/Shire**: 2019-2024: Hemophilia clinical launch  
**Gates Foundation**: 2011-2017: Oral polio vaccine (**FDA, CDC**)  
**Johnson & Johnson** 2016-2018: Topical drug delivery  
**Novo Nordisk**: 2014-2016: Hemophilia clinical Development  
**JDRF/ADA**: 2011-2018 : Diabetes/retinopathy  
**Bayer**: 2010-2014: Hemophilia – global award  
**USDA**: 2002-2014 Chloroplast genome & engineering

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**Successful mentees pursuing their passion at SIVB conference  
San Diego, July 2022, or lab group celebrations**



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**Ace2 Chewing Gum in the News: 2021-2022**

Featured in global attention with >200 news releases including in >100 global languages - Reuters, BBC, CNN, NBC, Fox, ABC, Times, WebMD, Yahoo News, Times of India, Scientific American, National Geographic, Scientific Russia, Asian Age, Galileu, India Today, Indian Express, USA Today, The Gazette etc. and >2 million Twitter exchanges in numerous global languages.



**Daniell Lab**  
Smruti Nair, Rahul Singh, Geetanjali Wakade, Amy Guo, Shina Lin, Rachel Kulchar, Venkata Mangu, Nataliya Balashova, Yao Shi  
**Ricciardi Lab**  
Hancheng Guan  
**Koo Lab**  
Zhi Ren  
**Mark S. Wolff**



**Wang Lab**  
Wan Zhou  
**Collman Lab**  
Jevon Graham- Wooten  
**Kenneth Margulies, William Short, Pablo Tebas**

**Funding:** NIH grants R01 HL 107904, R01 HL 109442, R01 HL 133191, Commonwealth of Pennsylvania and IDEA award to Henry Daniell

**Science - Editor's Choice**



Pulmonary Hypertension  
Feature, Clinical Implications – American Heart Association award  
NIH SMARTT Clinical Award

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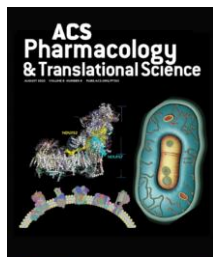


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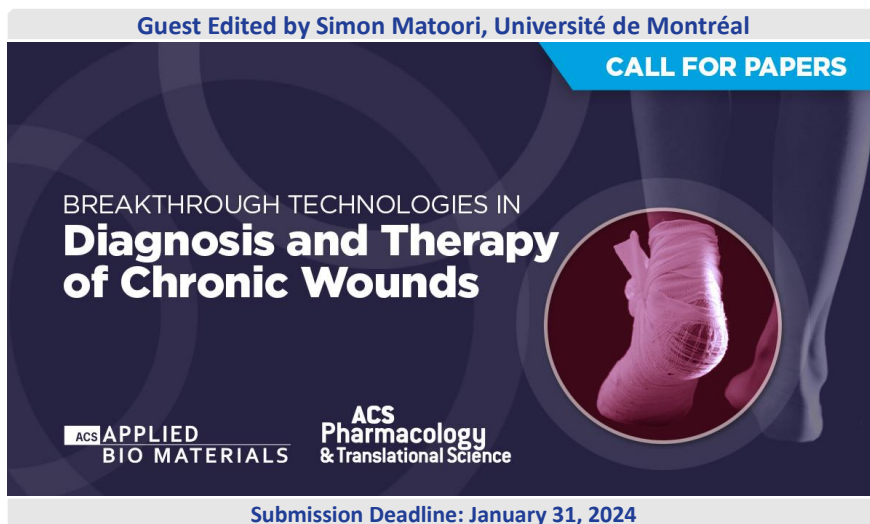
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