just [insul]in case

MAKING BIOLOGICS ON-DEMAND

1

THE TEAM


Anthonia Azubike


Jeffrey Banaszak


Amanda Dinh


Hanna Lefebo


Karen Nguyen


Andrew SyBing

2

Biologics On-Demand

Insulin as a prototype for implementing this new manufacturing system in emergencies.

Lifesaving medications prepared on-demand to **save lives and reduce cost.**

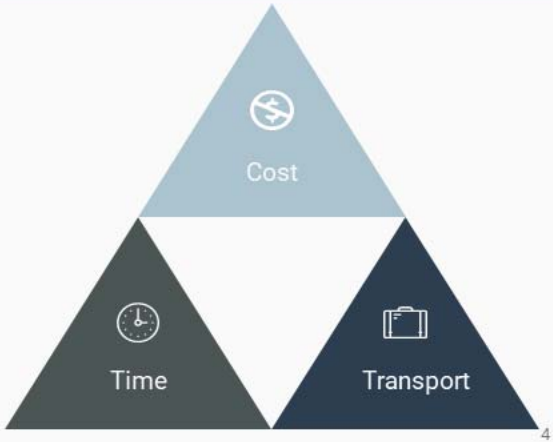
Proposal:
Leverage existing FDA policies to expedite the approval of emergency drug manufacturing.

3

3

CURRENT ISSUES

- **Lack of domestic manufacturing**
- **Emergency drug stockpiles**
- **Shipping drugs to areas in crisis**

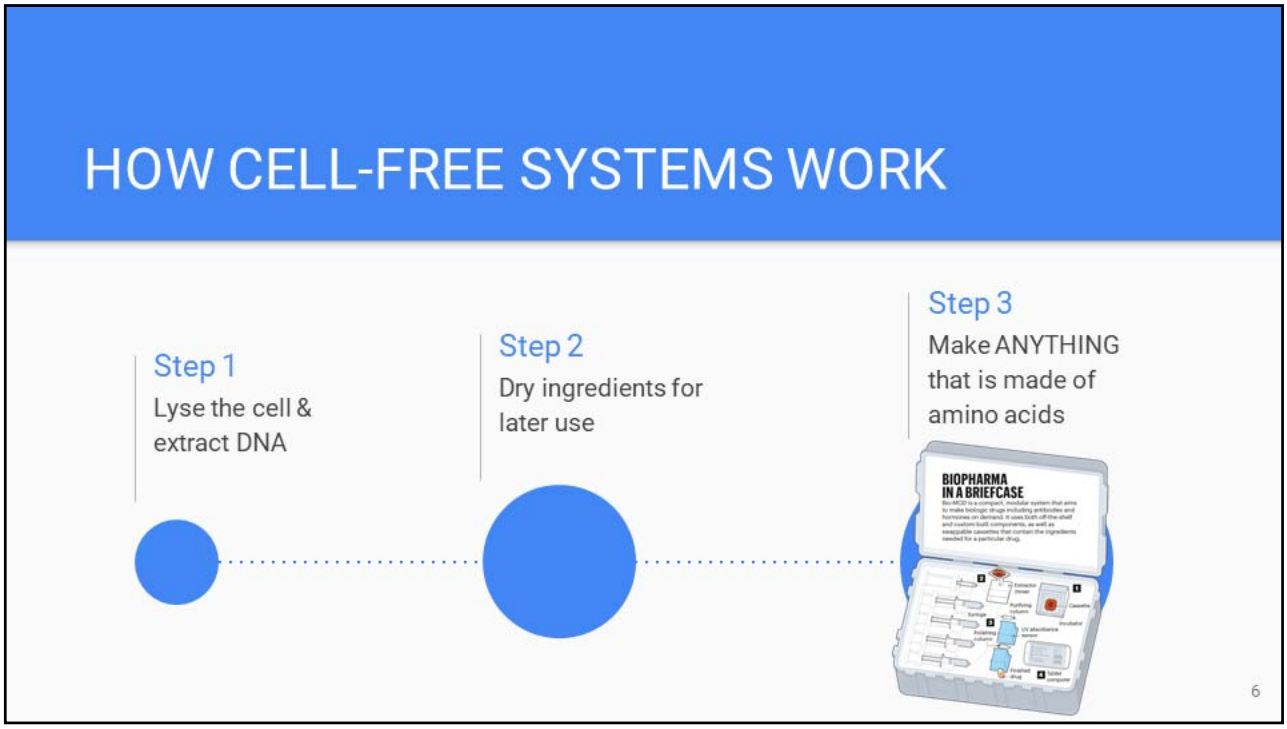


4

4


SOLUTION:
Biologics On-Demand
"I wanted to have a machine that could make any drug, at any time, in any quantity."
Geoffrey Ling, former doctor, U.S. Army, and current CEO, On Demand Pharmaceuticals
5
35 inch
14 inch

5


HOW CELL-FREE SYSTEMS WORK
Step 1
Lyse the cell & extract DNA
Step 2
Dry ingredients for later use
Step 3
Make ANYTHING that is made of amino acids
BIOPHARMA IN A BRIEFCASE
6

6

MAJOR CONSIDERATIONS

Feasibility?

Training?

Drug selection?

Barriers to access?

7

7

New regulatory classification: **"mobile site"**

8

8

REGULATORY PROPOSAL

Combine FDA policies to

expedite the manufacturing of inaccessible drugs in an **emergency**

- Animal Efficacy Rule
- Emergency Use Authorization
- fGMP

9

9

INSULIN AS *PROTOTYPE*

- **Life-Saving & Essential**
- **Insulin Manufacturing Standards**
  - Well-studied
    → save time & money on trials
  - Confident in determining purity

Prevent harm to patient

10

10

11

THANK YOU

TO OUR WONDERFUL MENTORS, JUDGES, UMBC COLLEAGUES, & M-CERSI

James E. Polli, PhD

Professor & Ralph F. Shangraw/ Noxell Endowed Chair in Industrial Pharmacy & Pharmaceutics, UMSOP, Co-Principal Investigator of UMD Center of Excellence in Regulatory Science & Innovation (CERSI),

Kimberly Maxfield, PhD

Policy Lead, Office of Clinical Pharmacology, CDER, Office of Translational Sciences, FDA

Silvana Borges, MD

Associate Director for Regulatory Science, Office of Drug Evaluation II – Immediate Office, OND, CDER, FDA

UMBC Bio-MOD Research Team

Dr. Govind Rao
Dr. Yordan Kostov
Dr. Leah Croucher
David Burgenson (PhD Candidate)

Alemayehu (Alex) Akalu, PharmD

Senior Staff Fellow, Oncology Program, Office of Hematology & Oncology Products, CDER, FDA

12

References:

https://www.prnewswire.com/news-releases/fda-understates-percentage-of-foreign-made-medication-sold-in-us-300551124.html

https://www.fda.gov/media/112395/download

https://www.fda.gov/news-events/press-announcements/fda-announces-key-actions-advance-development-novel-coronavirus-medical-countermeasures

https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#cgmp

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

https://www.pharmavoice.com/blog/biologics-market-growth/

https://cen.acs.org/biological-chemistry/biotechnology/Making-biologics-demand/96/i45

https://directorsblog.nih.gov/2018/10/08/how-to-make-biopharmaceuticals-quickly-in-small-batches/

https://fortune.com/2016/08/05/portable-device-could-make-biotech-drugs-on-demand/

https://www.nature.com/articles/d41586-019-03455-x

https://www.reuters.com/article/us-health-coronavirus-fda-chloroquine/u-s-fda-says-malaria-drugs-in-shortage-as-coronavirus-drives-up-demand-idUSKBN21J5RX