just [insul]in case
MAKING BIOLOGICS ON-DEMAND

THE TEAM

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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.

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CURRENT ISSUES

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

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
MAJOR CONSIDERATIONS

Feasibility?
Training?
Drug selection?
Barriers to access?

New regulatory classification: “mobile site”
REGULATORY PROPOSAL

Combine FDA policies to expedite the manufacturing of inaccessible drugs in an emergency.

Animal Efficacy Rule

Emergency Use Authorization

fGMP

INSULIN AS PROTOTYPE

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

Prevent harm to patient
# Future Implications

- Save Time
- Save Money
- Save Lives
- Extends to other biologics

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5/26/2020
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