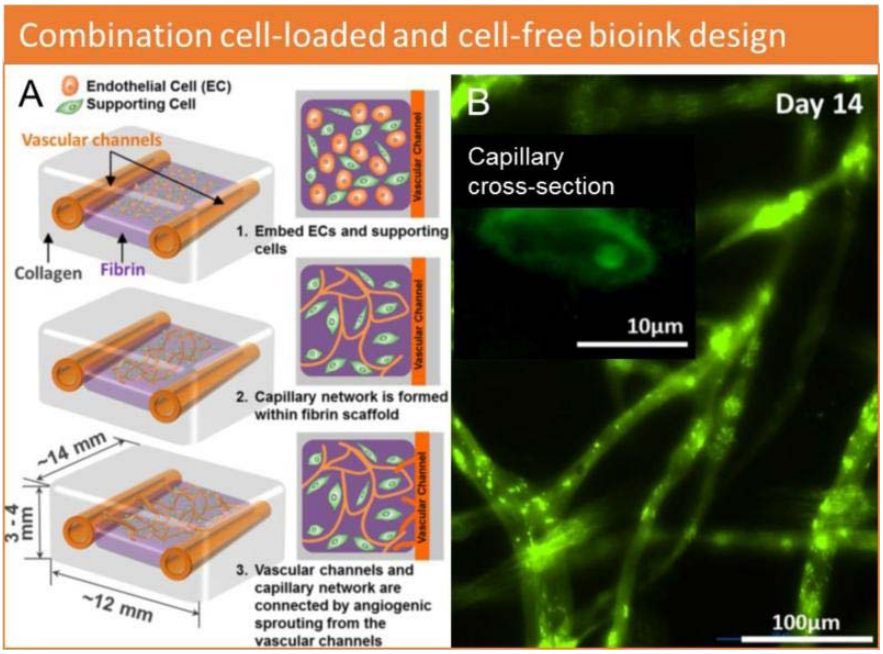
Scalable Biofabrication of Human Tissue

April 2018 Tech Brief for Life Sciences Talent Network



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5124424/figure/F8/

Regenerative Medicine Comes of Age

Biofabrication is already here in the large-scale production of medicinal biologics (e.g. the heavily advertised Humera and Enbrel), vaccines and reconstructed **human skin**. Small scale biofabrication is available in the form of cell therapies and personalized medicine, wherein one's own cells are altered and re-injected into the body.

The next level of sophistication will be in **3D printing** of **organs**. Additive manufacturing techniques like 3D printing allows the organ "designer" to create with a complexity that manual manipulation cannot achieve. This will lead to new careers and generate new career pathways in the organ biofabrication business.

Labor Force Takeaway

New therapies made possible by **biofabrication** may not be able to utilize the same distribution schemes as do traditional pharmaceuticals. Organs-for-transplant distribution is not scalable. Biofabricated tissues may need to be dispensed at specialty pharmacies. If this is the case, the number of specialty pharmacies will grow quickly.

Considering a career pathway in specialty pharmacies is a worthy thought experiment. Perhaps they will grow out of pharmacy schools and stay under their auspices. Perhaps they will grow out of hospital pharmacies. If they go the way of Humira and Enbrel, that's a very different model. Watch and track.

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Biofabrication –not just for biologics anymore

This brief expands on last month's essay on biochips which use biofabricated tissue. Growing tissues and organs in a production facility (biofabrication) followed by implantation in an ailing body, is well on its way to widespread reality. There are many drivers for this branch of translational medicine. Consider two:

- If a regenerated organ's cells are derived from the patient's own cells, two problems could be resolved. First, the issue of degrading health while waiting for donor organs is minimized. Second, the need for medication to prevent organ transplant rejection is eliminated.
- Biofabrication produces a uniformity of cells for testing toxicity and drug efficacy. For example, reconstructed human skin is currently used for cosmetics testing, avoiding the need for testing on animals. Human-on-a-chip, while highly ambitious, would drastically reduce the cost of analysis. It could also improve response prediction of new compounds in individuals and in general.

While pharmaceutical companies appear to be focusing on biologics and cell therapies, new biofabrication entrants are coming from outside the bio-pharma sector. L'Oreal is a leader in tissue engineering or "SkinCeuticals". Although most of their tissue R&D takes place in France, L'Oreal has a strong presence across NJ. A buildout of their Episkin and SkinEthic technologies could also come to NJ. If so, workforce readiness will play a part.

Modern Meadow has moved from NYC to Nutley, NJ. They have not entered the therapeutic tissue market, but they do grow leather from collagen. A look at their workforce and workforce needs could provide insight for development of career pathways.

NJ has all the elements needed for SkinCeuticals, biofabricated organs and similar markets to develop and grow. Proactively considering career readiness and pathways could be a catalyst.

Bioprinting provides the ability to place cells or biological material where it needs to be to grow into an organ. It will be a tool for screening and model construction in the next few years. Furthermore, 3D printers and bioinks have already been developed and are commercially available.

Soon enough the question of how to distribute biofabricated living products will have to be considered. Walgreens and CVS are not set up to dispense cell therapies much less organs. The biologics Humira and Enbrel are shipped to patient's homes and live in the refrigerator until they are self-injected. Other biologics are dispensed like chemotherapy – through IV in a supervised setting.

Personalized medicine has to be dispensed through a specialty pharmacy. Whether they grow out of schools of pharmacology, hospitals or independent clinics, they will create a new set of career paths.

Chances are that the industry will grow much more rapidly than legislators or insurance companies can react. If so, price pressures will have more effect on biofabricated materials than they do on traditional pharmaceuticals. This opens up possibilities for entrepreneurs.

Forward planning could help New Jersey's workforce keep pace with the growth that biofabrication could experience in roughly five years as the industry expands.

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