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Rethinking Pharma and Biotech Outsourcing

A call for data security and supply chain resilience

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In the realm of pharmaceuticals and biotechnology, the Biosecure Act looms large, casting a shadow of uncertainty and urgency over the sector.[1] This proposed legislation, introduced in both the Senate (S.3558) in December and the House of Representatives (H.R.7085) in January, aims to restrict U.S. companies from relying on certain contract research organizations and contract development and manufacturing organizations located in China, including the prominent WuXi AppTec, as well as BGI Group, MGI Tech, and Complete Genomics.

As a recent news story in *Nature Biotechnology* noted, the ban could extend to institutions that receive funding from the NIH or other U.S. government

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agencies, which would include almost all universities, research centers, hospitals, and life sciences companies.[2] The potential ramifications of such a measure are profound, with the potential to disrupt supply chains and derail drug discovery and development efforts on a national scale within the current outsourcing landscape.

Supply chain implications

The reality is stark: many pharma and biotech companies have turned to contract research organizations and contract development and manufacturing organizations located in China for efficiency and affordability, often outsourcing critical aspects of their operations. However, recent allegations of intellectual property leaks have sounded a clarion call, underscoring the vulnerabilities inherent in this dependence on such entities in certain jurisdictions for crucial research and development functions.

The specter of supply chain disruption, as exemplified by the logistical challenges brought about by the COVID-19 pandemic, also looms large in the minds of industry stakeholders. The concentration of manufacturing and research activities in distant locales poses inherent risks, leaving companies vulnerable to unforeseen disruptions.

The Biosecure Act serves as a poignant reminder that safeguarding intellectual property and data security must be paramount considerations in any outsourcing strategy.

Development implications

One potential solution is to go the way of many other industries: digital and encrypted. How would this work for drug development and manufacturing?

Forward-thinking digital chemists have been crafting the printing press for molecules and chemicals, a word processor, and auto-correct in order to bring the archaic, manual field of chemistry up to date. By introducing a chemical coding language and secure online data repository, the molecule design and manufacturing process could move away from traditional laboratory environments toward a fully digital, highly reproducible model.

In such a system, a chemical description language could tell a computer compatible with any batch chemistry robot how to synthesize a drug—similar to how HTML gives instructions to the browser in your laptop. Rather than relying on scant supplies of high-demand, hard-to-access drugs, those in developing countries would be able to access a “recipe” to produce the molecules needed at the push of a button.

This dream is already a reality in a specific and limited capacity. As governments around the world were scrambling to secure supplies of the COVID-19 treatment remdesivir, for example, digital instructions for whipping up a batch of the nearly 400-atom molecule were available on the open source repository Github, freely available to anyone with the hardware needed to execute the chemical program.

The wider adaptation of this approach—in individual labs and/or larger-scale manufacturing facilities in key biotech centers—could foster collaboration, accelerate the pace of discovery, and enhance precision and efficiency across the entire chemical development process. Importantly, it would also enable greater agility in response to evolving market dynamics and address the vulnerabilities associated with far-flung outsourcing.

By embracing digitalization, prioritizing data security, and reimagining traditional paradigms, the drug development and manufacturing industry could face a future defined by resilience, agility, and unparalleled scientific discovery.

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