The Daily Dish

Biopharma Security and China

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As the old saying goes, you can lose a lot of money betting on Congress getting something done. (Actually, Eakinomics may have made that one up.) Anyway, at the moment, the exception that proves the rule would appear to be the BIOSECURE Act. The bill would prohibit agencies from contracting with "biotech companies of concern" as well as from contracting with a firm that uses said equipment or services. It would also place similar prohibitions on federal loan and grant dollars.

As detailed in this insight from AAF's John Walker, the proximate reason for the bill is the failure of Chinese biopharma firms to protect Americans' genetic data. As a result, the initial drafts of BIOSECURE simply barred any transactions with particular Chinese firms. Given the bipartisan anti-China sentiments, the (rational and otherwise) desire to onshore supply chains, and the desire to look good prior to the election, it would seem that the BIOSECURE Act will move this summer or fall.

Now comes the hard part: drafting a workable policy. To begin, it is not feasible to simply cut ties with Chinese firms and shift activity domestically. The United States simply does not have the capacity. Per Walker, "Roughly 83 percent of the top 100 prescribed generic medications are imported, with antibiotics and antivirals being the most import dependent." In contrast, China is a leading source of pharmaceuticals, accounting for 23 percent of total imports. Also, a key component of the pharmaceutical manufacturing chain is active pharmaceutical ingredients (APIs). APIs tell a similar story. The United States has only four of the 103 sites capable of making 30 or more APIs. In comparison, China has more than double the number of production facilities capable of producing 30 or more APIs, and China provided roughly 17.8 percent of U.S. API imports in 2019.

So, it would take a long time to transition manufacturing from China to the United States. Accordingly, the most recent versions of the BIOSECURE Act provide for a lengthy transition period as existing contracts are wound down.

One might think that ties could be severed more quickly by shifting contracts to another non-U.S. manufacturing giant. A seemingly promising candidate would be India. Alas, as Walker writes:

> While India is a substantial and trusted source of generic products, a recent enforcement action should give us pause about over-reliance on Indian manufacturers. In July 2023, the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research Office (CDER) sent a warning letter to Intas Pharmaceuticals, an Indian-based, multinational pharmaceutical manufacturing company with roughly $2.8 billion in annual revenue. In the letter, CDER cited Intas for several "significant violations" of Current Good Manufacturing Practice (or CGMP, a regulation system of minimum requirements for assuring proper design, monitoring, and control of drug manufacturing processes and facilities) stating that the firm's quality control unit "failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity." This letter came as a follow-up to a surprise inspection of Intas' facilities where the FDA found an analyst had destroyed

> documents “by pouring acetic acid in a trash bin containing analytical balance strips” and that Intas’ management showed an “egregious pattern” of shortfalls, demonstrating the firm’s inability to carry out “basic responsibilities.”

This leaves the issue of biopharma security in a typical place: a popular but unworkable – at least in the near term – policy that is very likely to pass.