BAHM 2027 Case FAQs

Q: Our program is based outside the U.S. How could we approach this case from a non-U.S.-centric angle?

You're welcome to bring a non-U.S. perspective. The case is about U.S. supply security, but the solution depends on allied nations. The case names friend-shoring as one of its two main levers, and it limits friend-shoring partners to countries with FDA-recognized or compatible regulatory standards, such as the EU, Japan, South Korea and Abraham Accords signatories. A team based in one of those places may know more than a U.S. team about which facilities are underused, how long it takes to qualify a site, what local permitting involves, and how its government would negotiate. Here are a few ways to use that:

- Design a joint or multi-country portfolio where your country is a co-investor, co-purchaser or regulatory partner rather than just a supplier.
- Show how U.S. measures could line up with your government's own policies on critical medicines, so allies aren't competing for the same limited capacity.
- Look at retaliation risk from a partner's side. If China or India restricts exports, what happens to your country's own drug supply when it sends volume to the U.S.?

Whatever angle you take, your plan will still be judged on whether it meets the case's goals: less single-country dependence for HHS-ASPR designated medicines within 18 months, protected patient access, and longer-term onshoring that has actually been started. A non-U.S. perspective should help you get there, not change what the goal is.

Q: What about taking the perspective of a near-shore or friend-shore provider, or a foreign subsidiary of a U.S. company?

Yes, that's a legitimate way in. It can make your analysis more concrete, especially on the economics of making low-margin generic ingredients outside low-cost countries. Two cautions:

1. **The deliverable is still a policy portfolio.** Use the provider's or subsidiary's view to show which policies would actually change an investment decision: advance purchase commitments, multi-year procurement contracts, mutual recognition of inspections, tolling agreements, tariff treatment and so on. Then recommend those policies.
2. **Watch the "first mile."** Many allied-nation and near-shore API plants still buy their KSMs or intermediates from China. If you move the API step but the starting materials still come from a single source, you haven't reduced dependence, you've only moved it upstream. Judges will look for supply chain mapping that goes all the way back to the KSM.

Q: Although the focus is on policy, could we develop a business plan for a pharma company trying to address the case's objectives?

A business plan can't replace the policy plan, but it can make it much stronger. One of the case's objectives is a financing and governance model that attracts sustained private capital despite thin generic margins. A firm-level pro forma is one of the best ways to show your policies would actually do that.

A useful approach is to treat the business case as a stress test of your portfolio. Show a representative API or KSM investment (returns, payback, break-even volume) with and without the policies you propose. For example, compare a no-policy baseline with a version that adds an advance purchase commitment, a price floor or reliability premium in procurement, faster site qualification, and tax incentives. That shows which tools matter most and what they would cost the government.

Keep the main 10-page plan focused on the policy portfolio and put detailed financial models in the optional appendix.

Q: India is the sole source for only a fifth of U.S.-approved APIs. Couldn't we propose moving more manufacturing from China to India?

First, a clarification on the numbers. The case cites analyses showing China is the sole source of at least one KSM for well over a third of U.S.-approved APIs, and India is the sole source for roughly *another* fifth. Together that's more than half, so India is part of the concentration problem, not a way around it.

Second, the case is explicit that the goal is to eliminate single-source *and* dual-country (China/India) dependence. Shifting volume from China to India would still leave the U.S. dependent on a single foreign source, which doesn't meet that goal. India also isn't on the case's list of example friend-shoring partners, and the case assumes India, like China, could restrict exports or retaliate within the 18-month window.

Third, much of India's API production depends on intermediates and KSMs imported from China. Moving API work to India without moving those inputs too can leave the underlying China dependence in place.

India can still have a role. A team could argue for Indian capacity as *one of several* diversified sources for particular molecules, as long as it shows that the KSM supply is independent of China and explains how India fits a portfolio that doesn't depend on any one country. A China-to-India shift as the main strategy, though, wouldn't meet the case objectives.

Q: Should we assume all pharma companies, many of them competitors, will support the new legislation? What if they don't?

No, you shouldn't assume broad industry support. Working out who will support or oppose your plan is part of the assignment. Political and diplomatic feasibility is an evaluation criterion, and governance and political durability is a required section.

"Pharma" covers groups with very different interests:

- brand-name innovator companies
- U.S. and foreign generic manufacturers, many of which depend on low-cost China and India supply chains
- contract manufacturers (CDMOs) and domestic API makers
- distributors, group purchasing organizations (GPOs) and PBMs
- hospital and pharmacy purchasers

Policies that raise input costs, such as tariffs, sourcing mandates or country-of-origin rules, may be opposed by generic firms working on thin margins, while domestic and allied manufacturers may support them. Strong submissions map these stakeholders and design around their interests. Examples include pairing requirements with incentives, phasing in obligations, offering reliability premiums in procurement, or building opt-in purchasing consortia.

Also note that the case doesn't hand you a specific bill. You're designing the portfolio and choosing its legal tools, whether that's new legislation, existing executive and procurement authorities, appropriations or contracting vehicles. If any of your mechanisms ask competing companies to coordinate (for example, joint purchasing or shared capacity reservations), say how you would handle antitrust concerns.