To: Dr. Peter Navarro
Assistant to the President for India and manufacturing Policy

From: James C. Gale
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Dr. Navarro,

Following are my brief thoughts on the nature of the U.S. drug supply problem and possible remedies.

Background

Signet is a private equity fund that provides growth capital to commercial-stage life sciences products companies. We currently have thirteen (13) companies in our portfolio whose activities range from producing active pharmaceutical ingredients (APIs) to contract development and manufacturing of pharmaceuticals to selling finished products. Our investments have been concentrated in the US and Europe with some activity in India. We have long played a role in the generics industry.

The Nature of the Problem

Over 75% of all prescriptions in the US are filled by generic drug. It is estimated over 50% of this product is produced outside the U.S. Why? Generic drugs are essentially commodities. Therefore, market share is garnered by being the lowest-cost producer. Historically, reliability of supply was also an important factor. But, with the changes in the US drug distribution process, price reduction has been the dominant factor in choosing vendors.

While the impact of the coronavirus has recently impacted Chinese API production, and concomitantly the availability of finished drug supplies, the loss of US control over its drug supply has previously been manifested (x-ref: the Valsartan issue last year). The long-term solution entails a re-evaluation of the incentives for manufacturers to participate in the US market. But in the short-term, the issue is ensuring continued availability of critical prescription anti-infective, cardiovascular and other life-saving drugs.

Proposed Actions: Short-Term

Following is a basic outline of steps we would recommend to deal with short-supply product. This is very simplistic:

1) Identify the Products which face drug shortages. Contact the three Big Source distributors (Claris One; Red Oak Sourcing; and Walgreens/Boots Alliance) for information about inventory in their system.
2) Prioritize the Products that need to be addressed.
3) Identify alternative sources of supply for these products either in the US or Europe.
4) If none, ascertain whether discontinued ANDAs (the generic licenses) can be found and reactivated by the original producers. Determine their source of supply.
5) To the extent the original API and finished dose producers can't or are unwilling to restart production, alternative producers will need to be procured.
6) The FDA need to adapt protocols for rapidly approving the reactivation of these products. Alternatively, they many need to provide waivers to source product from Europe and elsewhere that is not specifically approved in the US.

Proposed Actions: Long-Term

To restore U.S. control of its supply chain necessary entails requires a restructuring of the drug distribution market. The prior Administration allowed the concentration of market power into the hands of a small number drug purchasers. This has led to a number of distorting effects. The consequence has been the demise of US generic drug producers with no attendant benefit to patients. Attempts are being made by affected parties to work around the issue (e.g., the creation of Civica; California's announcement of establishing an alternative buying group). This requires a broader discussion than in this memorandum. But, the long-term solution to restoring US generic drug production should probably include the following elements:

1) Create a mandate that a portion of certain critical drugs be produced in the US.
2) Rebalance market power so the lower drug costs should benefit patients not distributors.
3) FDA should harmonize inspection standards and penalties of foreign facilities with those applied to the US.
4) Anti-competitive pricing practices of foreign suppliers should be penalized.