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**Hon. John Kerry,**  
**U.S. Secretary of State**

**Dear Secretary Kerry,**

**SUB: US-INDIA AS STRATEGIC PARTNERS IN DELIVERING GLOBAL HEALTHCARE**

**Introduction: Healthcare – an area of strategic importance**

Trade discussions between USA and India have covered an extensive range of sectors and issues of strategic relevance. However, one area of significant strategic importance viz. Healthcare especially the Pharmaceutical sector, has been overlooked. The two economies have an unencumbered opportunity to partner and make an enormous difference to global healthcare.

Access and affordability are the two pivotal points around which health economics revolves. No economy can boast of a sustainable and equitable healthcare system that delivers high quality healthcare without imposing fiscal challenges on the exchequer. Obamacare and Medicare are no exceptions. Europe is struggling to deliver on its social agenda for healthcare and India is yet to roll out a National Healthcare system. The world needs innovative and affordable solutions to deliver on the promise of a fundamental “Right to Healthcare”.

The Indian Pharma Industry has earned the proud label of being the “Pharmacy of the World” by virtue of being the largest and lowest-cost producer of generic drugs for the benefit of patients the world over.

The US has been christened the “Fountainhead of the World”, providing a continuous pipeline of innovative solutions to enhance outcomes as well as address unmet medical needs.

India and USA are therefore natural synergistic partners in building a sustainable and affordable global healthcare paradigm.



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### **US-India Pharmaceutical Partnership: Perceived threats have hijacked this opportunity**

Generic drugs of Indian origin account for 30% of US prescriptions, thus endorsing the relevance and significance of Pharmaceuticals in our trade relations.

This is reflected in the number of USFDA accredited pharmaceutical manufacturing facilities. At the last count, India had ~370 USFDA approved plants which is the largest number outside the US.

Despite the above statistics, India's profile as a strategic Pharmaceutical partner has remained elusive. US Pharmaceutical Trade Bodies like PhRMA and BIO have lobbied relentlessly to impose market restrictions on Indian Pharmaceutical companies through several protectionist measures including the recent veiled threats of downgrading India to USTR's 301 Priority Foreign Country category. Organizations like The Gates Foundation, Clinton Foundation and others, on the other hand, have relied extensively on Indian Generics to address their global healthcare programs.

The contentious issue that has stalled any dialogue of partnership in the Pharmaceutical arena is one of Intellectual Property (IP). Although India is fully TRIPS compliant, there have been demands on India to do better. US Pharma companies have strongly objected to India's laws facilitating the manufacture of generic drugs and India's commitment to promote global access to healthcare. The dichotomy lies in the dilemma of whether a block buster drug is one which sells a Billion Dollars (the Developed World version) or one which treats a Billion Patients (the Developing World version).

The high price expectations of US innovators inevitably leads to tension in developing world countries like India where patients and Governments are unable to afford what US and European Administrations are able to support. However, the recent uproar over US Pharma Company Gilead's exorbitantly priced Hepatitis C drug, *Sovaldi*, has reached a tipping point where Payors like Express Script's Chief Medical Officer, Steve Miller said "If we don't change the basic pricing structure of pharmaceuticals, this system will collapse."

Data from a 2013 US Report on Generic Drug Savings (which of course includes Generics from other countries including the US) shows that generic pharmaceuticals saved the US health system and patients \$217 billion in 2012 and a staggering \$1.3 trillion dollars in the most recent decade. Generics and Biosimilars therefore are key to reducing the US drug bill and are integral to meet the objectives of The US Affordable Care Act.

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### **Fostering US-India Pharma partnership: Leveraging key enablers**

The US medical and pharma eco-system has a significant representation of ethnic Indian doctors, scientists, pharmacists, engineers and technicians. Likewise, the Indian eco-system has a growing proportion of Non Resident Indians from the US, many of whom are US citizens. This makes for an ideal platform for partnership.

The Indian Pharma Industry has created a global scale manufacturing sector which has provided India a globally competitive advantage. This has seen a number of US Generic companies investing and acquiring manufacturing capacity in India. Eg. Mylan, Hospira, Abbott etc. Indian companies likewise, have also invested significantly in establishing both manufacturing and distribution organizations in the US thus creating a number of jobs in the US Pharma sector.

The scientific talent pool in India has also created a Research Services eco-system which has been tapped by a diverse number of US pharma companies spanning small start-ups to large MNCs. The most notable of these are BMS, Abbott, Baxter, Amgen, Pfizer, Merck, GE Medical etc. This has provided a significant cost arbitrage which has added enormous value to US drug innovation.

It is noteworthy that key patented drugs are being produced by Indian Contract Manufacturers that provide innovator Pharma companies a huge cost advantage.

Indian IT services are also playing a key role in supporting the US healthcare system especially in the area of Electronic Medical Records and Data management.

**The Indian Pharma industry has a key partnership role to offer the US in improving health economics. It is therefore important for bi-lateral discussions to recognize this important dimension and foster closer co-operation both at the government and business levels.**

Yours sincerely,

**Kiran Mazumdar-Shaw**  
**Chairperson**  
**CII National Committee on Biotechnology**

**Copy: U.S. Secretary of Commerce Penny Pritzker**