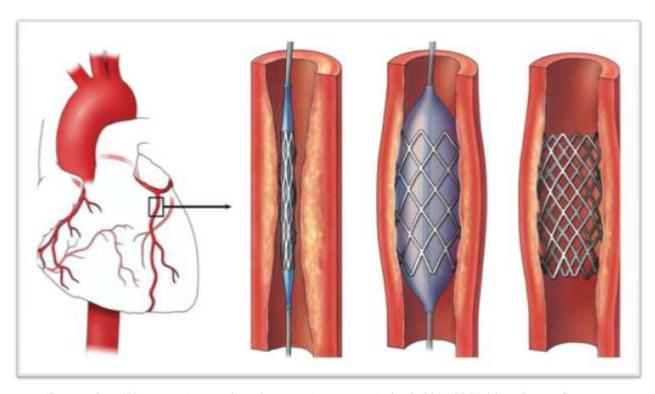
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# Regulation of Coronary Stent prices: An unfinished battle



 $(\textbf{Source -} \underline{\text{http://i2.wp.com/geographyandyou.com/wp-content/uploads/2016/08/Petitions-Power-Coronary-stent-prices-to-come-down.jpg?fit=1600\%2C890)}$ 

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### **Lead Essay**

### Regulation of Coronary Stent prices: An unfinished battle

In February 2017, the National Pharmaceutical Pricing Authority (NPPA) passed an order with immediate effect, which slashed and fixed the prices of Coronary Stents in India. A coronary stent is a 'short wire-mesh tube' which is primarily used in survivors of heart attacks and in patients with blocked arteries. It helps in opening the blocked arteries and allows regular flow of blood from the heart. NPPA has capped the prices of Drug-eluting Stents (DES) at Rs. 29,600 and the Bare Metal Stents at Rs. 7,260. Further, "Institutions such as hospitals/nursing homes/clinics utilizing Coronary Stents shall specifically and separately mention the cost of the coronary stent along with its brand name, name of the manufacturer/importer/batch no. and other details, if any, in their billing to the patients or their representatives".

Previously, the price of stents ranged anything between Rs 23,000 and Rs 2.5 lakh per piece. Here, the highest profit margins were made by the hospitals at up to 654%. Though both the varieties of stent are metal wire-mesh, the DES variety is of superior quality. It is coated with medicine which is periodically released to prevent any further arterial blockage in the heart. The DES variety covers nearly 80% of the market share for coronary stents implanted in India. iii As per the survey conducted by IMS Health on behalf of Advanced Medical Technology Association (AdvaMed), it was reported that stents account only for 25% of an angioplasty's bill. Whereas, "about 15% of the bill is the hospital margin on stents and 60-67% make up for hospital charges, including the doctor's fees, etc". iv During the consultative meetings with the stakeholders, NPPA had also observed, "huge unethical mark-ups are charged at each stage in the supply chain of Coronary Stents resulting in irrational, restrictive and exorbitant prices". The Chairman of NPPA, Bhupinder Singh has assured the manufacturers that the capped prices have a provision of an 8% profit margin. vi In July 2016, the Ministry of Health had announced their decision to include all kinds of stents in the National List of Essential Medicines in order to bring down the prices of the product. vii In April 2016, the Core Committee had submitted its report to the Government, in which it had examined the issues relating to the essentiality of Coronary Stents. In the report they had observed, "there is very high incidence of coronary artery disease (CAD) in India associated with high morbidity and mortality; and that CAD has become a major public health problem; and that Percutaneous Coronary Intervention (PCI) procedure requiring coronary stent implantation is an important treatment modality for the management of CAD, and hence coronary stents are 'essential' for public health'. viii

The above measures were the direct outcome of the Public Interest Ligation, filed by an Advocate Birender Sanghwan. The petition was filed because previously the drug manufacturing companies did not mention the maximum retail price on the Stent packaging and neither did the hospitals mention the price of the stents in the bill. This led to hospitals charging and extracting exorbitant prices for stent implants from their cardiac patients. Additionally the petition had demanded for ceiling the price for all stents. Therefore, after hearing the petition, in December 2016 a bench of the Delhi High Court had ordered the Centre to fix maximum retail price and a ceiling price for cardiac stents by March 1, 2017. The property of the court had ordered the Centre to fix maximum retail price and a ceiling price for cardiac stents by March 1, 2017.

#### The artificial scarcity of Stents

Following the notification by NPPA to cap the stent prices, the scarcity of stents in the hospitals in cities such as Mumbai have been reported. The high-end stents have been withdrawn from some hospitals to avoid price control. Similarly, the third and fourth generation stents were unavailable to patients on the pretext of price relabeling, despite NPPA notifying that relabeling is not required. Further, some hospitals are being flooded with the cheaper first and second generation of stents. The state-level Food and Drug Administration (FDA) is carrying out informal surveys for compliance of price capping and availability of implants at hospitals. Moreover, it has also been reported that manufacturers and distributors of the high-end stents, such as Synergy, Alpine, Absorb etc, have informed the FDA officials that the latest stents cannot be made available within the price range fixed by the NPPA.

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Therefore, following the reports of artificial stent shortages, NPPA has notified the Department of Pharmaceuticals to invoke the powers of Section 3 (i) of Drug Price Control Order, 2013. Under this section, 'the government can regulate distribution and direct any manufacturer to increase production and sell products to institutions, hospitals or any agency as the case may be in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest'. Further, the manufacturers are required to submit a weekly report on stents produced and distributed, to NPPA and Drugs Controller General of India (DCGI).xi

The NPPA has also issued show-cause notices to Max Hospital, Saket (New Delhi), and Nidaan Hospital, Sonipat (Haryana) over complaints by patients for overcharging for stents. Similarly, the authorities have initiated probe against some reputed hospitals, including PGIMER, Chandigarh, Lilavati Hospital in Mumbai; Max Hospital, Metro Hospital in Faridabad (Haryana) and Shri Ram Murti Smarak Institute of Medical Sciences in Bareilly (Uttar Pradesh). However, the regulatory authorities will proceed further only if the preliminary investigation indicates violation. If a hospital is found guilty of overcharging for stents, 'the NPPA has the power to recover the overcharged money along with 15% interest under the provisions of the Drugs Price Control Order'. Xii

#### Unnecessary stents being implanted

The regulation and capping of the stent prices in India is commendable but just a half-battle won. The price regulation will only make the stent implants cheaper and affordable. But, the major concern over the practice of irrational stent implants or an angioplasty continues to persist. The use of cardiac stents in India has been growing rapidly at 25 per cent annually. According to the Cardiology Society of India, in 2015 as many as 4,20,000 angioplasties were performed in India. According to experts, in the majority cardiac patients with even 50% blockage in arteries who do not require stents are implanted with stents. XiV

A few years ago, in a country like USA which has better monitoring and oversight of medical procedures than India, a study had reported that only half the non-emergency cardiac stent implants were appropriate. In India, where there is hardly or no regulation of hospitals in this regard especially in the private sector, at least 25-30% of the stent implants are inappropriate. Hence, it indicates towards unethical stent implants being a serious concern for cardiac patients. In order to curb the unethical practice, in 2009, an expert panel of cardiologists in the USA published criteria for appropriate use of stents. This had a positive impact, and USA has witnessed a remarkable decline in the number of inappropriate stent implants. Similarly, some experts are of the opinion that the Cardiology Society of India should frame similar guidelines for the appropriate use of stents in India.<sup>xv</sup>

According to Prof B. M. Hegde, Cardiologist & former Vice-Chancellor of Manipal University, is of the opinion that 'the only area where angioplasty has a proven track record is during an acute heart attack and during such times also, the procedure has to be done within minutes. Rest of the time, it is done just to make money by frightening patients and their relatives saying that there are blocks in the coronary arteries'. xvi

#### Conclusion

The measure to cap the stent prices in India is commendable. However, this may also lead to increase in the overall packages by some private hospitals for stent implants in the form of hospital and surgical charges, to increase their own share of profit. This might make the procedures unnecessarily expensive despite the stent price caps. Moreover, as it is being reported that some hospitals are resorting to use first and second generation of stents instead of the better third and fourth generation stents. Therefore, the state-level FDA authorities have to strictly regulate and probe the hospitals and the grievous complaints being filed by patients for overcharging and use of inferior quality of stents. Additionally, the Government needs to take measures to promote and provide incentives to the Indian drug manufacturing companies to compete in the stent market, which is largely dominated by foreign companies.

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Though having slashed the cost of stents by over 85% may reduce certain percentage in the number, but it is not a guarantee for the protection of patients against unnecessary stent implants in India. The government needs to frame strict guidelines and make audits mandatory for such procedures. The doctors and hospitals involved in these unethical practises should be seriously dealt with under the law. Unless the patients are protected from doctors and hospitals extracting unethical profits by performing unnecessary stent implants, the struggle for comprehensive healthcare for coronary artery diseases will remain incomplete.

#### Prepared by:

Abhishek Jain

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## **Headlines**

# As Security Violations Erupt, Operator of India's Biometric Database Stands at Troubling Crossroad

(Srinivas Kodali, The Wire, February 25, 2017)

On the streets of Hyderabad, one can purchase an Aadhaar number or a copy of an Aadhaar card for as little as Rs 5 per copy from small traders – xerox shops and the like. 'Data brokers' in Delhi and Mumbai, if one goes by well-sourced rumours, offer the same in larger quantities and at bulk rates. This was sparked in some measure after demonetisation, when the demand for Aadhaar numbers and a number of other identification cards was at an all-time high.

Read More: https://thewire.in/111869/indias-largest-biometric-database-turns-delhi-police-help/

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### **Economy**

### Paytm says it now has over 200 million users, aims for 500 million by 2020

(The Scroll, February 27, 2017)

Digital payments company Paytm on Monday said it had over 200 million users its wallet and other services. In a post on Twitter, Paytm founder Vijay Shekhar said the company was adding at least 700,000 digital wallets a day, with the total balance of all wallets being Rs 899.11 crore. The company currently has 106.8 million wallets with card or money saved on them, Shekhar said. "Next milestone, 500 million by 2020," he added. In a blogpost on January 1, the company had said it had 177 million wallet users by December 2016, with over one billion transactions through 147 million transacting users. The company also reported two billion user sessions and said it had registered more than two million merchants for its platform.

Read More: https://scroll.in/latest/830406/paytm-says-it-now-has-over-200-million-users-aims-for-500-million-by-2020

Date Accessed: 27/02/2017

# Bank union forum with 10 lakh employees to strike on Tuesday to protest bad loans, job outsourcing

(The Scroll, February 27, 2017)

A bank union forum covering 10 lakh employees across the public, private and cooperative sector is likely to go on strike on Tuesday to protest against various issues, including the rising number of bad loans and the outsourcing of permanent jobs in the sector. The United Forum of Bank Unions, an umbrella body of nine organisations, is also opposing labour reforms proposed by the Centre and is demanding greater accountability for senior executives, PTI reported on Sunday.

Read More: https://scroll.in/latest/830348/bank-union-forum-with-10-lakh-employees-to-strike-on-tuesday-to-protest-bad-loans-

job-outsourcing

Date Accessed: 27/02/2017

#### Time to consolidate inflation indices

(R. Gopalan & M.C. Singhi, Live Mint, February 26, 2017)

India currently has five consumer price indices (CPIs), three of which are population-segment specific CPIs, namely, CPI-IW (base 2001) for industrial workers, CPI-AL (base 1986-87) for agricultural labour, and CPI-RL (base 1986-87) for rural labour. CPI-IW, covering manual workers engaged in specified industrial sectors, is available at 78 selected centres and at all-India levels while CPIs AL/RL are available in 20 specified states and at all-India levels. As none of these indices provide inflation data for the entire population, the Central Statistics Office (CSO) of the ministry of statistics and programme implementation in 2011 began compiling new CPIs, one for the entire urban population, namely CPI-U, and the other for the entire rural population, i.e. CPI-R. These new indices are compiled at state/Union territory and all-India levels.

Read More: http://www.livemint.com/Opinion/rzFUCXkE7ffTkrU0xXvs2L/Time-to-consolidate-inflation-indices.html

Date Accessed: 27.02.2017

### India's Business Policy Needs to Look Beyond World Bank's Doing Business Report

(Prateek Sibal, *The Wire*, February 23, 2017)

In his Budget speech, finance minister Arun Jaitley devoted an entire section to the ease of doing business in India and proposed a number of reforms that could improve India's rankings in the World Bank's annual Doing Business report. Lately, the government has been proactive in streamlining the regulatory aspects of doing business in India and aims to be in the top 50 ranked countries from its current rank of 130 out of 190 countries. The urgency is such that ministries responsible for each of the ten parameters on which the World Bank ranks a country's business environment are holding weekly meetings to rapidly implement reforms.

Read More: https://thewire.in/111431/india-business-policy-beyond-world-bank/

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## **Governance & Development**

#### POLITICS AND GOVERNANCE

#### In this Bundelkhand Village, a Cry for Food, not Development

(Neha Dixit The Wire, February 22, 2017)

"Have you heard of kangaali mein aata geela? That is our situation," says Sugha Singh as he sits outside Balwan Singh's house along with other village men under the tree on a warm February afternoon. He is referring to an old Hindi idiom which means getting into more hardships one after another. They are mourning the death of Munni Devi, 78, who died on the first death anniversary of her son, Balwan Singh. Last year, on the same day, he committed suicide after he came back from his fields. His gram harvest was half of what he had expected. He was slated to pay Rs five lakh loan-Rs 2.5 lakh for the tractor and Rs 2.5 lakh for the farmers's credit card from the bank. His fourth of the six daughters was to get married next month and there was no money. He came home and consumed pesticide.

Read More: https://thewire.in/111194/bundelkhand-village-cry-food-not-development/

Date Accessed: 27.02.2017

#### SOCIAL AND ECONOMIC EXCLUSION

# The Life of Labour: Uber, Ola Strike Called Off in Delhi, Cleaning Sewers Claims Three More Lives

(Venkat T., Srividya Tadepalli & Thomas Manuel, *The Wire*, February 26, 2017)

Cleaning sewers has claimed the lives of three more people in Mumbai. *Hindustan Times* reported that, "Navsarjan, a group campaigning for safer working conditions and compensation for such workers, estimates that there were six such deaths in Karnataka last year. Ahmedabad reported an average of 20 deaths every year. Many more cases go unreported." Despite there being a law prescribing prison terms and harsh fines, criminal cases are usually never filed against those who force men into this kind of work. The last month has seen numerous strikes and protests by sanitation and safai workers attached to municipal corporations all over the country. The corporation of Aurangabad delayed paying its workers for 21 days due to "non availability of funds". In Surat, 2800 safai karamcharis were on strike to attain permanent status. Despite working for five years, the corporation keeps these workers on short-term contracts. They are paid Rs 154 for 4 hours of night work during the period of contract, according to *Times of India*.

Read More: https://thewire.in/112038/life-labour-uber-ola-strike-called-off-delhi-cleaning-sewers-claims-three-lives/

Date Accessed: 27.02.2017

#### HEALTH

#### What Policymakers Can Do About Healthcare in Rural India

(Deepanshu Mohan, The Wire, February 24, 2017)

A recent study by Jishnu Das and Aakash Mohpal offers a comprehensive look at severe deficits in healthcare quality in India, using case studies from Madhya Pradesh, Delhi, West Bengal and Tamil Nadu. In most of rural India, doctors are untrained and providers may prescribe high rates of antibiotics. The findings of the study are central to shifting the mainstream discourse. Rather than merely building public clinics, there should be a focus on measuring access to high-quality healthcare in rural areas. Moreover, as Das and Mohpal argue, quality measures based on a random sample of healthcare providers may not reflect the quality of providers that people most commonly use.

Read More: https://thewire.in/111658/healthcare-rural-india-policy/

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### **Governance & Development**

### Pain is the Silent Epidemic India's Health Systems are Failing to Handle

(The Scroll, February 27, 2017)

Every fifth person is likely to be suffering from some kind of pain, according to estimates of the World Health Organisation's Global Burden of Disease study. More than 20% of the world's people have headaches, more than 13% have migraines, 7% have lower back pains, almost 5% have neck pains, and 3% have osteoarthritis, the study said. Chronic pain is defined as any pain that lasts for more than three months. By some estimates, it affects at least 10% of the world's population, although this might be an underestimation due to lack of representative and reliable global data.

Read more: https://scroll.in/pulse/829320/pain-is-the-silent-epidemic-that-indias-health-systems-are-failing-to-handle

Accessed on: 28.2.2017

#### **ENERGY**

#### As solar shines, time to balance generation

(Vivek Sharma, Live Mint, February 26, 2017)

Last week, the winning bid for a solar project in Rewa, Madhya Pradesh, offered a levelized tariff of about Rs 3.3 per unit (with first year tariff at Rs 2.97). That's 24% cheaper than the Rs4.34 per unit offered by the winner of the Bhadla solar park project in Rajasthan in January 2016.

Such a plunge in tariff was made possible only because the developer, under a power purchase agreement, has been assured of the following: timely and complete payment security, prevention of shutdown of the solar power plant during grid instability or unavailability of transmission line, ensuring free land availability for construction, and assuring transmission or evacuation facility for off take of power.

 $\textbf{Read More:} \ \underline{\text{http://www.livemint.com/Opinion/fjYwmTHqsq3zT8ldrhUnzL/As-solar-shines-time-to-balance-generation.html}$ 

Date Accessed: 27.02.2017

#### AGRICULTURE

### Farmer's Notebook: Young India Can Save the Future of Agriculture

(M.J. Prahu The Wire, February 23, 2017)

Over a century old, the historic Tamil Nadu Agricultural University (TNAU) in Coimbatore has seen many remarkable individuals in the position of vice chancellor. Many have come and gone in the past decades. The coveted post entails dealing with technocrats, labourers, academics and students alike. During their term, vice chancellors are the face and emblem of the university.

Read More: https://thewire.in/111075/farmers-notebook-young-india-can-save-the-future-of-agriculture/

Date Accessed: 27.02.2017

#### LAW AND JUSTICE

#### **Protecting the rights of tribals**

(Pushkar Anand & Amit Kumar Sinha, The Hindu, February 27, 2017)

While the legislation for the protection of the rights of tribal people are in place, they are regularly flouted as has been highlighted by the Xaxa Committee report of 2014. Instead of ensuring that tribals are not ousted from the land to which they are historically and culturally connected, the state becomes more concerned about fulfilling contractual obligations towards the private investor. This means that constitutional and legal principles are discarded. This is evidenced by the increasing number of MoUs being signed by natural resources-endowed states with investors for facilitation of developmental projects. For instance, Chhattisgarh and Jharkhand have reportedly entered into 121 and 74 such MoUs, respectively, with various private players as of 2014. All this materially alters the role of the state vis-à-vis the tribal people as the state prefers economic expediency at the cost of the rights of tribal people.

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## **Governance & Development**

Read More: http://www.thehindu.com/opinion/op-ed/protecting-the-rights-of-tribals/article17372134.ece?homepage=true

Date Accessed: 27.02.2017

#### **Making the Punishment Fit the Crime**

(The Economic and Political Weekly, February 25, 2017)

In the absence of clear and organised sentencing guidelines, contemporary penal policy in India is marred by unguided judicial discretion. While this may be a matter of independent inquiry, it is an inevitable consequence of flawed legislative prescriptions regarding sentences under criminal law. The arbitrariness in prescribing maximum sentences in criminal laws is an issue that has received inadequate attention.

Read more: http://www.epw.in/journal/2017/8/commentary/making-punishment-fit-crime.html#sthash.2dOj1qiV.dpuf

Date Accessed: 28.2.2017

#### **DEFENCE**

#### Ways of sharing

(The Hindu, February 27, 2017)

India's decision to allow its border roads in Mizoram and Tripura to be used by Bangladeshi forces as they construct border outposts in the inhospitable terrain of the Chittagong Hill Tracts shows just how far the two countries have come to bridging their trust deficit. The decision, conveyed last week in Dhaka during the meeting of Home Ministry and security officials working on closer border management cooperation, came as Foreign Secretary S. Jaishankar flew into Bangladesh to begin preparations for Prime Minister Sheikh Hasina's visit to India in early April. If the visit goes as planned, it will be her first bilateral trip to India since 2010, when the MoU for the Land Boundary Agreement was originally signed. The terms of that agreement have now been fully implemented, and Ms. Hasina's visit will build on the boost that relations received from the historic agreement that was signed in 2015 during Prime Minister Narendra Modi's visit to Dhaka.

Read More: http://www.thehindu.com/opinion/editorial/ways-of-sharing/article17372178.ece

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## **Society**

#### **GENDER**

### 'Over 50% Indian women labour on without being paid'

(Business Standard, February 21, 2017)

Over 51 per cent of work done by women in India is unpaid and not counted in national statistics, with some estimates even putting this proportion at 85-92 per cent, says a report by the high-level panel set up by the UN Secretary General.

Read More: http://www.thehindubusinessline.com/economy/economy/article9553985.ece

Date Accessed: 27.02.2017

#### **Female Education**

(The Economic and Political Weekly, February 25, 2017)

Article 26 of the Universal Declaration of Human Rights is perceived as an important tool for women's empowerment through which women can break different sociocultural barriers. But a qualitative study conducted among 45 married urban women in Delhi and Yamuna Nagar district of Haryana explains how education is used to maintain the existing gender hierarchies and gender division of labour. It highlights that reproduction and transformation of social structures are evident in a novel manner where ideas of women's emancipation and subordination coexist.

Read more: http://www.epw.in/journal/2017/8/notes/female-education.html#sthash.JzuHCxKv.dpuf

Accessed on: 28.2.2017

#### Inequality, Gender and Socio-Religious Groups

(The Economic and Political Weekly, February 25, 2017)

Being of the female gender could mean a little less inequality in the Indian labour market now than belonging to a marginalised socio-religious group, observes this paper. It shows that more women are now in high-paid jobs, while groups such as Scheduled Castes/Scheduled Tribes and Muslims are still engaged in menial low-paid jobs. Over the years, there has been a decline in gender inequality and a rise in socio-religious inequality. A decomposition analysis reveals that education and type of employment contribute most to income inequality.

Read more: http://www.epw.in/journal/2017/8/special-articles/inequality-gender-and-socio-religious-

groups.html#sthash.80yOeCje.dpuf

Accessed on: 28.2.2017

## How Community Dialogue Can Improve Indian Women's Menstrual Health

(Swati Saxena, The Wire, February 24, 2017)

One health issue which is poorly understood and even less talked about in India is menstrual health and hygiene. Lack of access to toilets, sanitary napkins and even awareness regarding the issue can pose a major health and safety risk for girls across the country. Around 90% of women are unaware of the importance of using sanitary napkins. 87% continue to use old pieces of cloth as absorbents, with the result being that 79% suffer from low confidence, 60% miss school and 44% feel humiliated.

Read More: https://thewire.in/111153/how-community-dialogue-can-improve-indian-womens-menstrual-health/.

Date Accessed: 27.02.2017

## 26 Years After Kunan Poshpora, Army Still Enjoys Immunity For Sexual Violence

(Mohammad Umar, The Wire, February 23, 2017)

Six of the Kashmiri women who were allegedly gang raped by Indian soldiers in 1991 have died, the remaining 17 survivors still await justice. Many independent investigations and fact finding missions (including the one led by a former chief justice of the Jammu and Kashmir high court – Justice Bahauddin Farooqi) have concluded that the Kunan Poshpora case has seen unprecedented proportions of ignorance with regards to normal investigative procedures that must be followed after such a crime.

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## **Society**

Read More: https://thewire.in/111344/26-years-after-kunan-poshpora-army-still-enjoys-immunity-for-sexual-violence/

Date Accessed: 27.02.2017

#### **ELDERLY**

## Senior citizens below the poverty line to get wheel-chairs, hearing aids (*The Indian Express*, February 23, 2017)

The Union government has proposed to come out with a scheme to give assistive devices such as tripod walking sticks, wheel-chairs and hearing aids to the elderly living below poverty line (BPL) from the coming financial year, a senior official said on Thursday. The scheme in this regard is currently being formulated, Anand Katoch, Director of National Institute of Social Defence, Ministry of Social Justice & Empowerment, said at an international conference on services to the elderly.

Read More: http://indianexpress.com/article/india/senior-citizens-below-the-poverty-line-to-get-wheel-chairs-hearing-aids-4539727/

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## **Opinions/ Books**

#### **OPINIONS**

#### A foreign policy of cruel populism

(Vijay Prashad, The Hindu, February 27, 2017)

The U.S. President's agenda is part of the emergence of a cruel populism that has emerged across the West, inaugurated by the Brexit vote in the United Kingdom. The heart of this cruel populism is that the people of the West have been ignored by their 'globalist' leaders, who care more for free trade deals than for the haemorrhaging of jobs in their own homelands. In this they are correct. What makes them cruel is that rather than actually get to the heart of joblessness — which is partly due to unshared productivity gains through mechanisation — they offer a harsh cultural agenda to solve an economic problem. It is hatred of Muslims and other religious, sexual and ethnic minorities that focus the attention of Mr. Trump and France's Marine Le Pen, Holland's Geert Wilders and Germany's Frauke Petry.

Read More: http://www.thehindu.com/opinion/lead/a-foreign-policy-of-cruel-populism/article17348551.ece

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