1. The Drug Lobby Is Getting Touchy About Drug Prices – Bloomberg Quint

In the mid-1990s, the American public turned against the tobacco industry. As documents emerged showing that tobacco executives had long known that cigarettes could kill even as they denied any link between smoking and cancer, the companies were buried under a blizzard of exposes, public opprobrium, and lawsuits. The denouement was the 1998 Master Settlement Agreement, in which Big Tobacco agreed to pay 46 states billions of dollars annually, in perpetuity, while curtailing certain marketing practices. (The other four states cut their own deals with the tobacco companies.)

In such a circumstance, you would expect pharma's lobbyists to race to the company's defense. But that's not what happened. Instead, PhRMA, the powerful drug lobby (full name: Pharmaceutical Research and Manufacturers of America) essentially disowned Marathon. The company's "recent actions are not consistent with the mission of our organization," its chief executive, Steve Ubi, told Drew Armstrong and Caroline Chen of Bloomberg news in an e-mail. He went on: "The leadership of the PhRMA board of directors has begun a comprehensive review of our membership criteria to ensure that we are focused on representing research-based biopharmaceutical companies that take significant risks to bring new treatments and cures to patients."

2. Of new drugs, safety and data exclusivity side-effects – The Hindu Business Line

Drugs are an integral part of the healthcare delivery system and indispensable for catering to the unmet medical needs of patients. At the same time, it is of paramount importance that such drugs that are administered to patients are safe and efficacious. To ensure this, every drug that is introduced in the market requires to be tested for both safety and efficacy through an intricate process of clinical trials and post-marketing surveillance. The question is: how much time is reasonably adequate to ascertain that a particular drug is safe for the population to which it is administered. The Government's recent plan to increase the "new drug" period from four to 10

years is a step in the right direction from the angle of ensuring patient safety. However, the move seems to have drawn unnecessary scepticism by the use of such confusing terms as “data exclusivity”. And while data exclusivity is a TRIPS commitment, extending the term of the “new drug” under Rule 122 E of the Drugs and Cosmetics Rules is certainly not data exclusivity.

3. **India needs a multi-payer system – Mint**
   The 2017 Union budget presented some major reforms crucial to the advancement of the health sector. The increase in allocation for the National Health Mission by 20% is unquestionably a commendable move to boost public health delivery in the country. It provides much needed relief from financial bottlenecks in health policies. Moreover, conversion of 150,000 health sub-centres into health and wellness centres, the introduction of two new All India Institutes of Medical Sciences (AIIMS) in the states of Gujarat and Jharkhand, and the adding of 25,000 postgraduate seats in medicine reflect meritoriously on the government’s resolve to prioritize the health sector. While these measures are a step in the right direction, they mean little for the immediate growth of the health sector. The budget notably missed out on drawing attention to the accessibility factor in the Indian health system. Decades of low spending on the health sector has resulted in massive out-of-pocket expenditure on health. The overall outlay still remains largely underfunded and there was no mention of any action plan for universal healthcare.

4. **14 more medical devices may see price regulation – The Times of India**
   After cardiac stents, around 14 more medical devices that are rampantly sold at inflated rates in hospitals, could see a price regulation in the coming months. The list includes orthopedic implants, intraocular lenses and artificial heart valves to consumables such as syringes, needles and catheters. The National Pharmaceutical Pricing Authority (NPPA) has begun scrutiny of such devices, even asking makers to log in every detail about their manufacture and cost. NPPA chairman Bhupendra Singh told TOI, "We are collecting data on these devices on a war-footing. It will give us a fair idea about the volume of consumption, cost of manufacturing and price at which they are supplied to a patient. Exorbitant pricing in the health system will be dealt with strongly." In terms of steep retail markups, orthopedic implants probably come closest to cardiac stents. A selected imported hip and knee implants easily see profit margins in the range of 500-1,000%, industry insiders said. Indian implants too are sold at margins of 200-500%, though surgeons often prefer imported types. The cost of intraocular lenses also varies widely depending on the hospital and the operating surgeon. Consumables, on the other hand, are not just sold at arbitrary MRPs, but also billed in bulk to add to the patient's bill.

5. **Will this year’s ‘Special 301 report’ Trump up something? – The Hindu Business Line**
   In two months, the United States’ Special 301 Report will be released. The US Trade Representative's (USTR) report assesses trading partners on their performance involving intellectual property (IP). And this annual IP report-card never fails to invoke vociferous reactions for and against it in equal measure. Earlier reports have had IP experts and advocacy groups claiming that no one’s afraid of this report. But pharma industry circles watch it closely for the damage it can do by providing ammunition to lobbyists, who attempt to put pressure on governments in the US and India to wrangle more favourable policies for their industry. With many Indian and American drug-makers selling medicines in both countries, there is no doubt this report can be loved or hated, but not ignored. Under the watch of the new Trump administration, this year's ‘Special 301 Report’ has generated much interest, even hope maybe, of an even-handed approach towards India. That shift is reflected in the submission made earlier this month by the Indian Pharmaceutical Alliance (IPA) to the USTR.

6. **New stent prices have enough margins: Bhupendra Singh, NPPA – The Economic Times**
   The National Pharmaceutical Pricing Authority recently slashed prices of coronary stents by over 75%. NPPA Chairman Bhupendra Singh explains to ET Pharma the rationale behind the move and its tough stance on compliance. A detailed record of proceedings of the NPPA meeting shall be

uploaded on Monday. NPPA considered all available options of price fixation of stents, including the landed cost, cost of production, price to distributors, etc. Our challenge was that most methods had some logic and some limitations. We have tried to stop profiteering through our latest notification and leave only reasonable profits to all stakeholders in the trade channel. Price capping will make stents more affordable and accessible to patients and new prices leave enough margins to the industry to grow, innovate and come out with new products as well.

7. **Regulator to probe bills, ensure patients gain from lower prices – The Times of India**
With reports of hospitals see king to beat the price cap on stents by shifting charges under other heads, the National Pharmaceutical Pricing Authority (NPPA) plans to seek billing data from the insurance regulator and insurance providers to ensure price reductions are passed on to patients. The drug pricing authority is in talks with the Insurance Regulatory and Development Authority of India seeking information on billing so that data can be analysed to detect possible circumvention of price caps. "Most patients who undergo angioplasty and procedures involving stents have in surance and claim reimbursement. Insurance companies therefore have all billing data.We are trying to tap that data to monitor the situation," a senior NPPA official told TOI. While hospitals and cardiologists were found earning most of the margins on stents, up to 650% in some cases, there are concerns hospitals will find ways to maintain profits under other heads. "We are taking all possible steps to ensure benefits are passed on to the patients and no artificial shortage is created," NPPA chairman Bhupendra Singh said. NPPA is hopeful billing data from insurance companies will also help track violations. For instance, it will show a sudden spike in bed charges. Or if the overall billing does not come down as a result of price control for stents, it will prompt authorities to investigate.

8. **Drug price regulator wants government to ensure stents supply – Mint**
The Indian drug price regulator has asked the department of pharmaceuticals to ensure the availability of coronary stents in the wake of reports that manufacturers may be creating an artificial shortage after stent prices were slashed by up to 85% earlier this week. The National Pharmaceutical Pricing Authority (NPPA) has asked the government to invoke Para 3 of the Drug Price Control Order (DPCO) to direct manufacturers and importers to maintain production, import and supplies of stents at the pre-price cap level, according to NPPA's official Twitter handle. A stent is a tiny tube-shaped device placed in narrowed or blocked coronary arteries to maintain blood supply. Para 3 of DPCO states that the government may direct any manufacturer to increase production and supply of a product in order to achieve adequate availability and regulate distribution in case of an emergency or in circumstances of urgency or in case of non-commercial use in public interest. After the government's decision to slash prices and enforce a single ceiling price for all the different variants of drug-eluting stents, manufactures and distributors started pulling off the high-end stents across the country, several media reports indicated.

9. **Indian biosimilar market likely to touch $1 billion in three years – Business Standard**
The Indian biosimilar market is poised for big growth, augured by the launch of new products, growing acceptance of biosimilars and the entry of new players like Aurobindo Pharma. It is expected to increase from $186 million in 2016 to $1.1 billion in 2020, according to industry estimates. Indian life science firms are investing in biosimilar development to tap this growing opportunity. They are also establishing manufacturing facilities in other countries to serve the local and export markets. Several of them are opting for acquisitions and alliances to get biologics skills and the latest manufacturing technologies to be able to succeed in the complex regulatory environment. Recently, Aurobindo Pharma has forayed into biosimilars development by acquiring four cell culture-derived products from Swiss firm TL Biopharmaceutical. With this, it is developing an overall portfolio of dozen biosimilars. Around 70 per cent of clinical trials of these products might happen in India, while the rest might take place in other countries.

10. **Indian pharma companies still wary of US drug market – The Economic Times**
In 2013 when Ranbaxy, one of India's oldest drug companies, agreed to the US Department of Justice's (DOJ's) charge of wrongdoing in its manufacturing process, a $500 million fine seemed like a small price to pay for what was coming. Ranbaxy became a stick for global competitors of Indian drug companies to beat the industry with the issue of "poor quality". It seemed that Indian companies would immediately be hit by Ranbaxy's actions; however, that tide had seemed to have passed, with large Indian drug makers speeding ahead with their growth in US markets because of the free market policy towards price control. Cut to 2015, when Indian drug makers' growth hit a speed bump because of manufacturing issues. While a couple of India's biggest pharma firms have their factories under import alert by the US Food & Drug Administration (USFDA), since November last year, a handful of other companies were put under investigation by the DOJ over alleged cartelisation.

11. **India's vaccine regulatory body NRAI gets highest WHO ratings – Business Standard**
The National Regulatory Authority of India (NRAI) has been given the maximum ratings by global health body World Health Organisation for vaccine regulations. WHO completed the assessment of the status of the Indian vaccine regulatory system against WHO NRA Global Benchmarking Tool (GBT) and measured the maturity of the system in India. "The assessment has been done in respect of 9 different functionalities and Indian NRA has been declared 'functional' with a maturity level of 4 which is the highest level as per currently evolved definitions in respect of 5 functions, and maturity level 3 in respect of 4 functions," an official statement said. While, maturity level 4 indicates good results and sustained improvement trends, level 3 reflects systematic process based approach, early stage of systematic improvements, data availability regarding conformance to objectives and existence of improvement trends, it said.

12. **Niti Aayog wants axe on homoeopathy, ayurveda bodies – The Economic Times**
Continuing with its drive to streamline the country's medical system, the Niti Aayog is expected to recommend scrapping of two more institutions — the Central Council of Homoeopathy (CCH) and the Central Council of Indian Medicine (CCIM). A senior government official told ET that the Aayog is working on two new bills suggesting ways to replace the two statutory bodies under the health ministry, which govern higher education in homoeopathy and Indian systems of medicine including ayurveda. A draft bill suggesting creation of an all-new body to replace the decades old statutory bodies is ready, but a final decision will be taken up by a Niti Aayog vice-chairman Arvind Panagariya-led panel set up to suggest sweeping reforms in the department of Ayush under the health ministry. Last year, the panel looked into the issue of poor regulation of education by Medical Council of India and proposed replacing it with National Medical Commission.

13. **A long way before we can trust mobile health apps, say experts in US – Daily News and Analysis**
Mobile health apps available today can test haemoglobin levels, tell whether a person has osteoporosis and even check their lung function. As per estimates by IMS Institute for Healthcare Informatics in 2015, there were around 1,65,000 mobile based health-care apps across the world, with a total of over one billion downloads. Mobile applications, in recent years, have become popular in the health sector. But while there are plenty of apps that provide information, there are also concerns about the quality of advice given to patients. "There are several hundred apps on mental health but very few with medical evidence. There is a huge opportunity to integrate science with these apps," said Gregory D Hager, Mandell Bellmore Professor, John Hopkins Whiting School of Engineering.

14. **Make healthcare a fundamental right: H Sudarshan Ballal – The Times of India**
India desperately needs a holistic care system that is universally accessible and effectively reduces out of pocket expenditure," declared Dr. H. Sudarshan Ballal, Chairman, Manipal Health Enterprises. Dr. Ballal was addressing a fair number of students, doctors and researchers at the conclave on 'Affordable Healthcare -- Building India's Future Health Economy', jointly organized by the Centre for

Corporate Governance and Citizenship (CCGC) and the Centre for Public Policy (CPP) at IIM Bangalore, along with SustainabilityNext, an e-magazine which provides relevant content from practitioners and thought leaders, on Saturday (Feb 18). "Even though, India is a developing nation we have diseases of both the developed and developing countries. We have not yet conquered communicable diseases like malaria, TB, H1N1, among others, and we are also hit by lifestyle diseases like diabetes, hypertension and heart diseases in a big way," Dr. Ballal said, emphasising that India's challenge was not bringing modern healthcare to the country, but in making it affordable and accessible to the majority of its citizens. "Just as our economic reforms have not touched the common man the healthcare boom has also failed to touch the common man and this is a dangerous social trend needs to be changed," he remarked.

15. **New Medical Devices Rules make Central Licensing Authority competent authority to licence Class C & D devices – Pharmabiz.com**

The Medical Devices Rules, 2017 which was recently notified by the Union Health Ministry has made the Central Licensing Authority (CLA) as the competent authority for providing licence for manufacture of Class C and Class D medical devices; while State Licensing Authorities have been given the authority to licence Class A or Class B medical devices. As per the newly notified Rules, medical devices of low risk have been classified as Class A; low to moderate risk as Class B; moderate to high risk as Class C; and high risk as Class D. According to the new Rules, which will come into force from January 1, 2018, the Central Licensing Authority shall be the competent authority for enforcement of these rules in matters relating to import of all Classes of medical devices; manufacture of Class C and Class D medical devices; clinical investigation and approval of investigational medical devices; clinical performance evaluation and approval of new in vitro diagnostic medical devices; and co-ordination with the State Licensing Authorities.