DOWNLOAD PDF THE PHARMACEUTICAL INDUSTRY AND ITS STAKEHOLDERS

Chapter 1 : How will the pharmaceutical industry evolve on drug pricing? | PBS NewsHour

Future of pharmaceutical value: hopeful despite recent innovation trends Advances in science and medical technology Genomics and personalized medicine can help treat diseases previously out of reach.

Population health impact was included by every firm as a source of motivation, either in the interview or in publicly available documents. In this case, CSR work preceded business presence and provided feedback that informed business strategies for expansion into this market. Others identified pre-commercialization CSR presence as a way of building trust with local governments, non-governmental organizations and consumers. This explains why new market entry considerations are intrinsically linked with external perceptions of a firm. Reputation was the most frequently and readily cited reason for CSR by all firms. All of the firms saw health, CSR, reputation and sustainability as interrelated. Firm A exemplifies this: From a commercial perspective, [â€¦] we feel very strongly that being socially responsible and engaging in activities that both advance our business objectives as well as social objectives really will help the company to be sustainable over the longer term. An employee exchange programs is one example of this engagement which can be described as corporate-sponsored volunteerism where in-house employees are placed with organizations in developing countries to help them with their organizational governance and development strategies. One respondent acknowledged the importance of recruitment and its ties to reputation, stating that his firm wants: Several respondents were determined that while creating economic value is essential to shareholders, CSR, philanthropy and CSV initiatives can all be mechanisms to benefit society simultaneous to commercial activities. Firm B has placed philanthropy under their larger CSR umbrella, noting that for healthcare companies the two come from similar motivations. In contrast, Firms A and D separated philanthropy and CSR indicating that philanthropy should be wholly benevolent whereas CSR seeks to create commercially sustainable models that can be mutually beneficial to the firms and the recipient societies. In Firm D, the respondent explained that CSR currently straddles three major divisions of the company: There was a clear lack of consensus on the definition of CSR. A handful of firms did define CSR, either in the interview or in official documents, each with different wording or even meaning. A few firms expressed frustration about misconceptions of CSR among stakeholders including implementing partners, governments, internal constituents and consumers. Critics, Firm F purports, are contributing to this impediment: Some but not all firms did report using guidelines developed by the Global Reporting Initiative, an international organization that promotes the use of CSR reporting as a way for organizations to become more sustainable and contribute to sustainable development. Several other firms also pointed to these indices as important incentives for CSR engagement by facilitating benchmarking of such activities. Firm F stated the specific annual goal of being among the top 3 companies in the industry on the Dow Jones Sustainability Index as a way of measuring and providing internal incentives for different departments. Discussion To the best of our knowledge, this paper provides the first portrait of why multinational pharmaceutical corporations are engaging in global health-related CSR activities. All six firms interviewed had extensive CSR experience encompassing diverse initiatives from mHealth to preferential drug pricing and employee exchange programs. Motivations offered by the firms can be generalized into three interrelated categories: Increasing access to medicines and treatments as a means to improving population health was the most commonly cited motivation for CSR endeavors in LMICs. This push for increasing access was closely linked to reputational benefit for the respondents, which the firms in turn connected to competitive advantage. CSR literature echoes many of the motivations cited in this study, including factors such as reputation building, opportunities for entering new markets and moral arguments to protect and better society [12 , 17 , 21 , 22]. This study showed that pharmaceutical firms struggle with how other actors perceive and define CSR and that CSR is not even understood in the same way across the pharmaceutical industry. While company respondents were aware and in some cases focused on the various indices tracking CSR, the lack of clarity around the definition of CSR

can be problematic for these indices too. The Dow Jones Sustainability Index is the best established of the various CSR-related indices discussed but its focus is more on corporate sustainability than public health concerns. In order to improve transparency and accountability, a common definition of CSR needs to be adopted by pharmaceutical and healthcare companies, and the Access to Medicine index measures of CSR effort need to be further developed. This study demonstrates that across the pharmaceutical industry, multinational corporations are making significant and diverse CSR efforts influencing health in LMICs. There are substantial further questions for research. First, while CSR initiatives are intended to deliver social benefits, it is possible that there may also be unforeseen consequences; for example, training certain health providers may squeeze others out of the labor market [24]. This study did not address the nature of CSR impacts on intended beneficiaries and research in this area would be worthwhile. Second, although pharmaceutical firms are building CSR initiatives on local partnerships, research is needed to investigate the extent to which such initiatives are truly aligned with local policies and priorities. Finally, our interviews and document review did not reveal data concerning the magnitude of resources currently invested in CSR and further investigation of the resources CSR requires is warranted. Limitations This was a small-scale exploratory study constrained by the resources available to the researchers. Nonetheless, we believe that the combination of interviews and document review provided a relatively comprehensive view of types of CSR activities conducted, organizational structures for managing CSR, and motivations for CSR across the sample of firms. It should be noted that only established companies with relatively mature CSR strategies were included in this study, and smaller companies with more nascent CSR initiatives may offer different motivations and perspectives. Conclusions This study highlights the increasingly important role that corporate social responsibility is playing in large pharmaceutical firms, and by extension in the health sectors of low- and middle-income countries. Furthermore, several of the factors unveiled in this study seem to limit the ability of the largest pharmaceutical companies to maximize their resources and will to improve the health of underserved populations. Our study points to three key steps that should be taken to help move forward the dialogue between the CSR arms of large firms and people concerned about public health in low- and middle-income countries. First, there is a need for clearer definitions of the many terms that are currently bandied around in this field, including philanthropy, CSR and CSV. Pharmaceutical companies suggest that misunderstanding of these terms leads to doubts regarding their CSR efforts and motivations, but it is clear that confusion also exists within the industry. Second, existing indices to track the development, implementation and effects of CSR strategies in the pharmaceutical sector should be strengthened. Of the available indicators the Access to Medicines Index is best aligned with public health interests, but needs more work in terms of garnering attention, promoting transparency and ensuring that the indicators truly reflect existing priorities and concerns. Finally, as detailed in the discussion, this exploratory study has suggested multiple further lines of enquiry, most of which would require country level studies to investigate in a more detailed way how specific CSR initiatives have engaged with country health systems and the impacts they have made. It is clear that as CSR grows in significance the global health community would be well-advised to invest more in understanding this important practice. Endnotes aSources included firm-produced financial statements and rankings from the following websites:

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Chapter 2 : STAKEHOLDERS IN PHARMACEUTICAL BUSINESS | Sarang S Bhola - www.nxgvision.com

Pharma companies operates like any other company. They are listed in stock exchanges. Any person who buys shares of Pharma company, is the stake holder of the company along with the employees.

Healthcare , Stakeholders Any person or institution directly or indirectly affected by the operation of the healthcare industry is considered a stakeholder. A healthcare stakeholder may be in contact with the healthcare provider or company on a regular basis or may intermittently touch base. Stakeholders are affected by change in systems, policies and practices in the healthcare industry. Customers Customers play a very important role in the healthcare industry. They are usually affected by business conditions. When the business conditions are positive, the company exerts its best effort to make greater profits and provides greater attention to its customers, trying to meet their needs in every way possible. Their interests are affected by the stability of the company. Thus, employees try to be wary and work diligently to keep their jobs. When the healthcare company is doing well, there is a great potential of rewarding employees, such as promotions and bonuses. Creditors Creditors are those people who have loaned their money to the healthcare company- either by producing raw materials for production or as cash. The company pays the interest of the creditors on their loans, regardless of whether the company generates profits. Typically, creditors hold the asset of the company for security. If the company fails to pay their loans, these creditors have the right to claim the assets. Creditors can lose their investments if the healthcare company declares a bankruptcy. Shareholders A healthcare company belongs to its shareholders, who have invested their money and bought the shares of the company. There is actually a direct rapport between their investments and the financial strength of the healthcare company. There are two classes of shares: Both types of shares are paid after the healthcare company has met its responsibilities such as paying the taxes and creditors, amortization and depreciation. Equity shareholders get to share the remaining or surplus profits. Preference shareholders are paid a fixed amount before dividends are paid to holders of common stock. Government The government also plays a vital role in the healthcare industry. It is considered a key shareholder in a healthcare business. In a liberal democracy, the government has the right to determine its responsibility in healthcare policy. The judgment of the government is checked by the voting public, which chooses leaders to represent the interest of the public. She has recently been researching online MBA Healthcare programs and reporting her findings to higher education blogs.

Chapter 3 : CISN - Drug Development - Stakeholders

Stakeholder theory Pharmaceutical industry Clinical trials Research participants Informed consent This is a preview of subscription content, log in to check access. References.

Sarang S Bhola Dr. Pharmaceutical industry is struggling for developing and maintaining the relation with the customers for that, sales representatives are trying to develop relation with all the stakeholders viz. Doctor, Stockiest and Retailers i. The ultimate consumer of pharmaceutical product is patient. Because actual business is comes from patients but most of the time medical practitioners, retailers are prescriber and decision makers and responsible for business. Present research paper deals with finding out the actual stakeholders in the pharmaceutical business. This paper will help to know the actual customer and consumers of pharmaceutical product which beneficial to marketers i. In current market situation many pharmaceutical organizations are using electronic media to develop and maintain the relationship with targeted customers. Sales representatives are developing the relationship not only with doctors but also with retailers and stockiest. In marketing, customer relationship management highlights the final customer of the product and in pharmaceutical marketing patient may be the final customer. But sales representatives are developing the more relation with Doctors, stockiest and retailers. Since, Doctors prescribes the medicines of particular company, Stockiest and Retailers play important role in distribution channels at the same time retailers can increase sale by communicating with nearest doctors about scheme or by substitute the prescription. Then, where is the final customer i. Sales representative never have a talk with patient but patients are purchasing the product and consuming the same. For maintaining relations with customers companies are investing a crore of rupees by offering valuable gifts, articles as well as tours. So, there is need to study the actual stakeholders and customer in pharmaceutical business. In marketing, the concept of Customer Relationship Management CRM highlights the final customer of the product and as far as consider the pharmaceutical marketing patient may be the final customer. But it is seen that sales representatives of this industry are developing the relation with doctors, stockiest and retailers rather than patient. Doctors prescribes the medicines of particular company while stockiest and retailers play important role in distribution channels and can increase the sale by communicating with nearest doctors about scheme or by suggesting substitute for some prescriptions. In this way sales representative never have any words with their final customer i. So it is essential to find out actual stakeholders in pharmaceutical industry. Customer of a pharmaceutical company can be divided into prescribers and non prescribers. The first group is mostly made up of general practitioners and specialists. The non prescriber group is made up of all parties who do not write prescriptions themselves, but have a direct or indirect impact on the prescribing process. Pharmacists may substitute the prescribed drug for the corresponding generic under certain conditions. Patients, the largest non prescribing group of all, who are gaining a similarly growing role in the prescription decision by consulting online medical education and suggesting a brand name to the physician. This group is however outside the scope of the proposed valuation approach as it will continue to require fundamentally different targeting and promotional approaches Meike et. The pharmaceutical market is strongly separated from traditional to fast moving consumer goods markets as buyer, consumer and decision maker are separated. In the case of a prescriptive drug the patient in fact is the consumer. Health insurance funds as reimburses constitute the payer side. Physicians who are prescribing the drug have the role of the decision maker. Therefore, the pharmaceutical industry comprises a complex network of customers. The customer network consists of physicians, care institutions and patients as customers in the proper sense. Further, stakeholder groups are pharmacists, health insurance funds, health-care policy and pharmaceutical wholesalers. Owing to their influence on prescription decisions, they should be considered as customers in a wider sense Christoph Burmann, Thus there are three main customer groups in pharmaceutical industry which include patients, physicians and payers Burmann, Christoph et. So present sales efforts in many pharmaceutical companies are oriented towards three customer segments first is physicians, second

hospitals, wholesalers and pharmacies, and third one is end customers, i. The doctor-patient relationship is central to the healing art of medicine Tanya et. Traditionally, pharmaceutical companies directed their marketing muscle at doctors who have the authority to write prescriptions, by using their sales representatives who are also known as detailers or drug representative Lundstrom, R. Physician is the primary target of most pharmaceutical companies relationship marketing efforts since physician plays the primary decision-making role and serving as an intermediary between the pharmaceutical firm and patient Melissa Clark, D. They opines that establishing relations with third-party allies has always been an important part of pharmaceutical company efforts, particularly in building support for products among healthcare professional groups. On the basis of above review researcher found that, doctors, medical representative, retailers, wholesalers, hospital staff and patients are the stakeholder in pharmaceutical business. Customer Centricity as a Key to Success for Pharma. Journal of Medical Marketing , Customer Relationship Management in the Pharmaceutical Insdustry: The Role of the Patient Adovocacy group. International Journal of Medical Marketing , 1 3 , Physicians Perception of Pharmaceutical Sales Representative: A Model fro Analysing the Customer Relationship. Journal of Medical Marketing: Device, Diagnostic and Pharmacetical Marketing , Relationship Quality in the Pharmaceutical Industry: Device, Diagnostic and Pharmaceutical Marketing , Is There an Elephant in the Room? Indian Journal of Medical Ethics. The need for a new go-to-market strategy in Europe: How to survive and thrive in the new more complex healthcare marketplace. International Journal of Medical Marketing ,

Chapter 4 : Who Are the Stakeholders in the Healthcare Industry? | How to Save Money

As stakeholders in the pharmaceutical industry, scientists who carry out biopharmaceutical research with the help of doctors, chemists and regulatory experts work together to ensure there is the successful development of a drug and it has been approved for consumption (Babler,).

Duties and Responsibilities of the Stakeholders Who are the stakeholders in the healthcare system? For the purposes of our discussion we define stakeholders as those entities that are integrally involved in the healthcare system and would be substantially affected by reforms to the system. The major stakeholders in the healthcare system are patients, physicians, employers, insurance companies, pharmaceutical firms and government. Insurance companies sell health coverage plans directly to patients or indirectly through employer or governmental intermediaries. Pharmaceutical firms develop and then market medications which are prescribed by doctors to treat patients. Typically they receive remuneration through insurance or governmental drug-benefit plans. Many employers offer health insurance coverage with varying deductibles and co-pays for their employees. Physicians are the providers of medical care; patients are the recipients. And government subsidizes healthcare for the elderly, the disabled and the poor. All stakeholders have duties and responsibilities. Clearly the interrelationship among the stakeholders in the healthcare system is rather complex. Two of the stakeholders, pharmaceutical firms and insurance companies, are publically owned corporations listed on the stock exchange. Their primary responsibility is to maximize stockholder wealth. Likewise, the primary goal of employers is to make money; however, their provision of health insurance for employees is a benefit, not a source of profit. Unlike the other stakeholders physicians have direct fiduciary duties and responsibilities towards their patients. Although they receive remuneration for their services, the doctor-patient relationship is a sacred trust that transcends monetary reward. Patients have rights, duties and responsibilities. Finally, democratic government has duties and responsibilities towards its citizens, but how they are defined in regard to the provision of healthcare is an evolving American story. Insurance Industry Currently rising premiums and strict requirements are keeping many people from obtaining health insurance. The insurance companies remain profit driven, but the nature of their service should not be profit focused. Adequate healthcare is becoming harder to obtain due to financial hardship. The insurance companies need to find an appropriate balance between their responsibilities towards both shareholders and patients. Quarterly reports for stockholders encourage the companies to focus more on profits than affordability. This causes insurance companies to have tight regulations against preexisting conditions so that mostly healthy individuals are selected for their plans. Such patients will not utilize costly procedures as often as individuals with chronic illnesses. However, this is unethical of insurance companies because it reduces healthcare to a profit centered industry, and prevents those in need from receiving care. Pharmaceutical Companies Pharmaceutical companies also play a key role in the healthcare system because many patients rely on their products. The prices for drugs are rising, and there are no caps to prevent them from reaching extravagant prices. The argument that the pharmaceutical companies need to charge ever higher prices to cover research costs is simply not true. Whether or not you argue that pharmaceutical companies have a moral responsibility to ensure that people can afford their products, at the very least they have the duty to be honest and practice fair marketing. Marcia Angell, previously an editor of the New England Journal of Medicine, has written extensively about the unethical behaviors of pharmaceutical companies. Let me cite one example. Through personal experience the author who had an office practice since the early s, witnessed a sinister change in the way pharmaceutical companies market their products to physicians. Previously they sent pharmacists with depth of knowledge about their products to objectively educate the physician about the benefits and risks of a particular brand medication. However, since the late s pharmaceutical firms send young attractive representatives with no formal training to market their drugs by establishing a social relationship with the physician and by offering incentives to prescribe their product. Many physicians whose prescribing practices

are unduly influenced by pharmaceutical representatives share the blame. They tend to respond to conversation about certain drugs rather than reading the biomedical literature. Physicians Physicians play a key role in ensuring that their patients receive adequate healthcare, but also in controlling the rising costs of healthcare. They have to find a balance between having a gatekeeper role for the insurance companies and being an advocate for the patient. Assigning a gatekeeper role to primary care physicians had the intention of lowering healthcare costs because fewer tests and referrals would be made. However, this is not working and it may be best to re-evaluate the role a primary care physician has in regards to referring patients. A coordinator role may be more beneficial than gatekeeper status. Also, since primary care physicians have increased the number of patients seen in a day to compensate for their decrease in revenue, this causes an increase in defensive diagnostic testing. The doctors do not have adequate time to review the chart or spend time with the patient, so they order more tests to reduce their liability risks. These actions cause healthcare spending to increase as well. By placing the physician between these two roles, a conflict of interest is created. Ethically, the doctor has a fiduciary duty to protect the interests of his patient, but in the current managed care environment, insurance companies give incentives to physicians to order fewer referrals and to cram more patients into each workday. It appears that money is at the center of our values. Physicians also have obligations to patients independent of insurance companies. A physician has an obligation of beneficence to do whatever is necessary to benefit his patient. Thus, the obligation of beneficence must be balanced by the principle of patient autonomy. Each patient is unique and has the right to participate completely in decisions about his health. Patients Patients also have an ethical responsibility towards their own health and towards controlling costs. While it would be impossible to implement a program that forced people to live healthy lifestyles, it is reasonable to assume that healthier living would lead to lower healthcare costs. Some companies, such as Wal-Mart and the WHO, have stopped hiring employees that smoke to reduce healthcare related costs. Often doctors are accused of over prescribing diagnostic tests, but this practice may be the result of patients who demand multiple tests even if some are unnecessary. As technology increases patients with insurance want the newest, most advanced, and expensive treatments that their insurance plan will cover, and oftentimes physicians succumb to their requests. The most expensive treatments are not necessarily the best, and the patient has a duty to participate with the physician in making reasonable and cost-effective choices. The Declaration of Independence seems to juxtapose two rights: Equalitarians emphasize the former; libertarians, the latter. Equalitarians hold that healthcare is a human right; libertarians hold that healthcare is a commodity. Equalitarianism emphasizes the role of government and is more appealing to democrats; libertarianism emphasizes the role of free market and is more appealing to republicans. The fundamental chiasm between these two contrasting ideologies which are operative in American culture remains an impediment to healthcare reform in the United States. The Cost of Pushing Pills: The Truth About the Drug Companies: Family Practice Feb 20 1: Medical Decision Making The Business of Medical Practice: Current Opinions in Critical Care Dec; 14 6:

Chapter 5 : Phase 2: Big Pharma expands its blockchain experiment | Supply Chain Dive

The pharmaceutical industry is one of the European Medicines Agency's (EMA) main stakeholders. Interacting with pharmaceutical companies has been a major part of EMA's daily business since it began operating.

Transcript Audio High drug prices are a constant consumer complaint about health care. Judy Woodruff sits down with Stephen Ubl, president and CEO of the Pharmaceutical Research and Manufacturers of America, at the Spotlight Health Conference at the Aspen Institute to discuss the Senate Republican health care bill, the prospects for lowering drug prices and the connection between the opioid crisis and the industry. As the battle over health care rages in Congress, one constant complaint from consumers is over drug prices. Judy Woodruff is in Colorado with our look at that issue â€" Judy. Stephen Ubl is its president and CEO. I sat down with him here at the Aspen Spotlight Health Conference today, and began by asking about the latest Republican plan to overhaul Obamacare. So, we will be very engaged in this discussion, and the prism with which we will look at it is making sure that patients have access to the breakthrough treatments and cures our industry is developing. The other major health care associations, hospitals, doctors and others have been pretty critical. Is the pharmaceutical industry alone in a way or almost alone in not being as worried, as critical of what the Republicans are doing? We heard President Trump during the campaign speak about the high cost of prescription drugs. One is ensuring that we continue to lead the world in developing better treatments and cures and, two, on jobs, ensuring that we have more domestic investment in the United States. And I think our industry is really poised to deliver on both those fronts. I think everybody agrees drug prices are out of control in this country. Drug companies have been sued, I know, by some state attorneys general, alleged collusion and rising prices. What is going on? What do you see is the problem here? So, if you look at Express Scripts, which is a leading PBM in the industry, pharmacy benefit manager, looking at spending in , drug spending went up 3. And net prices are up 2. So, if you went two or three years, prescription drug spending was actually the lowest growing or slowest growing category in health care. We did go through a spike in and , I would argue, due to some anomalous factors. FDA approved a number of new drugs. And a new cure for hepatitis C was introduced, which revolutionized the treatment of that disease and will obviate the need for liver transplant, as well as reduce the incidence of liver cancer. The python has sort of digested the tennis ball. At the same time, a lot of finger-pointing going on in the health care industry between the drug companies, the pharmacy benefit managers, hospitals, insurers. A lot of those fingers are being pointed, though, still at your industry. We think there are â€" we take these issues very seriously. And we think there are pragmatic, consumer-oriented solutions to address some of the issues that have been raised. So, for example, a lot of the media attention in the last year is focused on companies that are really nothing like our member companies. They are companies that are taking old drugs without market competition and raising the price dramatically. And we think there are policy solutions, primarily at the FDA, that would address those situations. Similarly, we think, as an industry, the pricing model needs to evolve. We need to move away from paying for volume to paying for the value of care. Payers want to move in this direction, our members want to move in this direction, providers want to move in this direction. Again, take cancer therapy. We want to be able to offer novel discounts. If you look at countries that have adopted models like the VA on a broad scale, the U. And we think that would be a movement in the wrong direction. So the VA, keep in mind, is a closed system, a small number, relatively small number of hospitals and consumers. As you know very well, I think something like 33, people died from opioid abuse in They expect the number to go up last year, this year, and so on. We know towns are overwhelmed. Critics are saying so much of this lies at the feet of drug companies that are promoting drugs that people get hooked on, and then those same companies minimizing or even trivializing the impact. How do you, as someone who sits in such a responsible position, look at this? But it is a multifactorial crisis. And is there going to be a change, do you think? Well, just to give you an example, the industry is in favor of mandatory training for health care professionals to learn more about pain management,

to learn more about appropriate prescribing. So we want to be part of the solution to this problem. Stephen Ubl, pharmaceutical manufacturers association, thank you very much. Listen to this Segment.

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Chapter 6 : Pharmaceutical industry - Wikipedia

Pharmaceutical industry is struggling for developing and maintaining the relation with the customers for that, sales representatives are trying to develop relation with all the stakeholders viz. Doctor, Stockiest and Retailers i.e. Chemist.

Pharmaceutical Industry in the U. Together with Canada and Mexico, it represents the largest continental pharma market worldwide. The United States alone holds over 45 percent of the global pharmaceutical market. In , this share was valued around billion U. Many of the global top companies are from the United States. In , six out of the top 10 companies were from the United States when based on pure pharmaceutical revenue. Interestingly, among the top pharma companies by revenue alone within the U. Regarding medical research and development, the U. Almost 60 billion U. Costs for developing a new drug have been increasing drastically over the last decades from under million U. Total nominal medicine spending in the U. In recent years, the three top therapy classes for which most money was spent included oncology, diabetes, and autoimmune. These three areas alone were worth over billion U. Based on the number of prescriptions, generics represent the top drugs. For example, Levothyroxine and Acetaminophen were prescribed a combined million times in Among consumers and patients, the pharmaceutical industry often leaves an ambiguous image. According to a recent survey among American adults, only 28 percent stated that their impression of the industry is positive, while 43 percent tended to have a negative impression. On the other hand, nearly 60 percent think that the quality of products manufactured by U. This text provides general information. Statista assumes no liability for the information given being complete or correct. Due to varying update cycles, statistics can display more up-to-date data than referenced in the text.

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Chapter 7 : U.S. Pharmaceutical Industry - Statistics & Facts | Statista

STAKEHOLDER ENGAGEMENT IN PHARMACEUTICAL INDUSTRY initiated by an organization with its stakeholders. The organization typically has many stakeholders, and is.

History[edit] Mids â€" From botanicals to the first synthetic drugs[edit] The modern pharmaceutical industry traces its roots to two sources. The first of these were local apothecaries that expanded from their traditional role distributing botanical drugs such as morphine and quinine to wholesale manufacture in the mid s. By the late s, German dye manufacturers had perfected the purification of individual organic compounds from coal tar and other mineral sources and had also established rudimentary methods in organic chemical synthesis. Epinephrine, norepinephrine, and amphetamine[edit] By the s, the profound effect of adrenal extracts on many different tissue types had been discovered, setting off a search both for the mechanism of chemical signalling and efforts to exploit these observations for the development of new drugs. The blood pressure raising and vasoconstrictive effects of adrenal extracts were of particular interest to surgeons as hemostatic agents and as treatment for shock, and a number of companies developed products based on adrenal extracts containing varying purities of the active substance. In , John Abel of Johns Hopkins University identified the active principle as epinephrine , which he isolated in an impure state as the sulfate salt. Industrial chemist Jokichi Takamine later developed a method for obtaining epinephrine in a pure state, and licensed the technology to Parke-Davis. Parke-Davis marketed epinephrine under the trade name Adrenalin. Injected epinephrine proved to be especially efficacious for the acute treatment of asthma attacks, and an inhaled version was sold in the United States until Primatene Mist. While highly effective, the requirement for injection limited the use of epinephrine[clarification needed] and orally active derivatives were sought. A structurally similar compound, ephedrine , actually more similar to norepinephrine , was identified by Japanese chemists in the Ma Huang plant and marketed by Eli Lilly as an oral treatment for asthma. Following the work of Henry Dale and George Barger at Burroughs-Wellcome, academic chemist Gordon Alles synthesized amphetamine and tested it in asthma patients in The drug proved to have only modest anti-asthma effects, but produced sensations of exhilaration and palpitations. Amphetamine was developed by Smith, Kline and French as a nasal decongestant under the trade name Benzedrine Inhaler. Amphetamine was eventually developed for the treatment of narcolepsy , post-encephalitic parkinsonism , and mood elevation in depression and other psychiatric indications. It received approval as a New and Nonofficial Remedy from the American Medical Association for these uses in and remained in common use for depression until the development of tricyclic antidepressants in the s. It was sold by Bayer under the trade name Veronal In , Hermann Emil Fischer and Joseph von Mering disclosed their discovery that diethylbarbituric acid, formed from the reaction of diethylmalonic acid, phosphorus oxychloride and urea, induces sleep in dogs. The discovery was patented and licensed to Bayer pharmaceuticals , which marketed the compound under the trade name Veronal as a sleep aid beginning in Systematic investigations of the effect of structural changes on potency and duration of action led to the discovery of phenobarbital at Bayer in and the discovery of its potent anti-epileptic activity in Phenobarbital was among the most widely used drugs for the treatment of epilepsy through the s, and as of , remains on the World Health Organizations list of essential medications. Today, amphetamine is largely restricted to use in the treatment of attention deficit disorder and phenobarbital in the treatment of epilepsy. In , Oskar Minkowski and Joseph von Mering found that diabetes could be induced in dogs by surgical removal of the pancreas. In , Canadian professor Frederick Banting and his student Charles Best repeated this study, and found that injections of pancreatic extract reversed the symptoms produced by pancreas removal. Soon, the extract was demonstrated to work in people, but development of insulin therapy as a routine medical procedure was delayed by difficulties in producing the material in sufficient quantity and with reproducible purity. The researchers sought assistance from industrial collaborators at Eli Lilly and Co. Walden of Eli Lilly and Company found that careful adjustment of the pH of the extract allowed a relatively

pure grade of insulin to be produced. Under pressure from Toronto University and a potential patent challenge by academic scientists who had independently developed a similar purification method, an agreement was reached for non-exclusive production of insulin by multiple companies. Prior to the discovery and widespread availability of insulin therapy the life expectancy of diabetics was only a few months. The drug was given the commercial name Salvarsan. Arsphenamine was prepared as part of a campaign to synthesize a series of such compounds, and found to exhibit partially selective toxicity. Arsphenamine proved to be the first effective treatment for syphilis , a disease which prior to that time was incurable and led inexorably to severe skin ulceration, neurological damage, and death. This work, also based in the testing of compounds available from the German dye industry, led to the development of Prontosil , the first representative of the sulfonamide class of antibiotics. Compared to arsphenamine, the sulfonamides had a broader spectrum of activity and were far less toxic, rendering them useful for infections caused by pathogens such as streptococci. These were developed by a U. The first diphtheria vaccines were produced in from a mixture of diphtheria toxin and antitoxin produced from the serum of an inoculated animal , but the safety of the inoculation was marginal and it was not widely used. The United States recorded , cases of diphtheria in resulting in 15, deaths. In parallel efforts by Gaston Ramon at the Pasteur Institute and Alexander Glenny at the Wellcome Research Laboratories later part of GlaxoSmithKline led to the discovery that a safer vaccine could be produced by treating diphtheria toxin with formaldehyde. Unsafe drugs and early industry regulation[edit] In over people died after ingesting a solution of the antibacterial sulfanilamide formulated in the toxic solvent diethylene glycol Prior to the 20th century drugs were generally produced by small scale manufacturers with little regulatory control over manufacturing or claims of safety and efficacy. To the extent that such laws did exist, enforcement was lax. In the United States, increased regulation of vaccines and other biological drugs was spurred by tetanus outbreaks and deaths caused by the distribution of contaminated smallpox vaccine and diphtheria antitoxin. This was followed in by the Pure Food and Drugs Act , which forbade the interstate distribution of adulterated or misbranded foods and drugs. A drug was considered misbranded if it contained alcohol, morphine, opium, cocaine, or any of several other potentially dangerous or addictive drugs, and if its label failed to indicate the quantity or proportion of such drugs. Massengill Company of Tennessee. The product was formulated in diethylene glycol , a highly toxic solvent that is now widely used as antifreeze. In response to this episode, the U. Congress passed the Federal Food, Drug, and Cosmetic Act of , which for the first time required pre-market demonstration of safety before a drug could be sold, and explicitly prohibited false therapeutic claims. The report concluded that "it appears that the use of antibiotics, early diagnosis, and other factors have limited the epidemic spread and thus the number of these diseases which have occurred". Percent surviving by age in , , and The dramatic decline in the immediate post-war years has been attributed to the rapid development of new treatments and vaccines for infectious disease that occurred during these years. The vaccine process was never patented, but was instead given to pharmaceutical companies to manufacture as a low-cost generic. In the United States Cancer Institute announced that it had concluded that SV40 is not associated with cancer in people. Severe cases of hypertension were treated by surgery. In researchers at Ciba discovered the first orally available vasodilator, hydralazine. In the mids Karl H. Baer, and Frederick C. Novello of Merck and Co. ACE inhibitors reduce the risk of new onset kidney disease [RR 0. The history of the development of oral contraceptives is thus closely tied to the birth control movement and the efforts of activists Margaret Sanger , Mary Dennett , and Emma Goldman. Based on fundamental research performed by Gregory Pincus and synthetic methods for progesterone developed by Carl Djerassi at Syntex and by Frank Colton at G. The original formulation incorporated vastly excessive doses of hormones, and caused severe side effects. Nonetheless, by , 1. The hearings covered a wide range of policy issues, including advertising abuses, questionable efficacy of drugs, and the need for greater regulation of the industry. While momentum for new legislation temporarily flagged under extended debate, a new tragedy emerged that underscored the need for more comprehensive regulation and provided the driving force for the passage of new laws. On 12 September , an American licensee, the William S. Merrell Company of Cincinnati, submitted

a new drug application for Kevadon thalidomide , a sedative that had been marketed in Europe since The FDA medical officer in charge of reviewing the compound, Frances Kelsey , believed that the data supporting the safety of thalidomide was incomplete. The firm continued to pressure Kelsey and the FDA to approve the application until November , when the drug was pulled off the German market because of its association with grave congenital abnormalities. Several thousand newborns in Europe and elsewhere suffered the teratogenic effects of thalidomide. Without approval from the FDA, the firm distributed Kevadon to over 1, physicians there under the guise of investigational use. Over 20, Americans received thalidomide in this "study," including pregnant patients, and about 17 known newborns suffered the effects of the drug. Manufacturers henceforth had to prove to FDA that their drugs were effective as well as safe before they could go on the US market. The FDA received authority to regulate advertising of prescription drugs and to establish good manufacturing practices. The law required that all drugs introduced between and had to be effective. An FDA - National Academy of Sciences collaborative study showed that nearly 40 percent of these products were not effective. A similarly comprehensive study of over-the-counter products began ten years later. Animal trials showed very good inhibitory effect as in clinical trials , however a long term study in dogs found toxic effects at higher doses and as a result mevastatin was believed to be too toxic for human use. Mevastatin was never marketed, because of its adverse effects of tumors, muscle deterioration, and sometimes death in laboratory dogs. By , Merck had isolated lovastatin mevinolin, MK from the fungus Aspergillus terreus , first marketed in as Mevacor. Researchers tested simvastatin , later sold by Merck as Zocor, on 4, patients with high cholesterol and heart disease. For his "pioneering research into a new class of molecules" for "lowering cholesterol,"[sentence fragment] [70] [71] Research and development[edit] Main articles: Drug discovery and Drug development Drug discovery is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen , and manipulating these pathways using molecular biology or biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions. Drug development refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate formulation and dosing , as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The cost of late stage development has meant it is usually done by the larger pharmaceutical companies. Smaller organizations, on the other hand, often focus on a specific aspect such as discovering drug candidates or developing formulations. Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances. More recently, multi-nationals are increasingly relying on contract research organizations to manage drug development. On the other hand, there were only 18 approvals in total in and 22 back in Since , the Center for Drug Evaluation and Research has averaged Drugs which fail part-way through this process often incur large costs, while generating no revenue in return. If the cost of these failed drugs is taken into account, the cost of developing a successful new drug new chemical entity , or NCE , has been estimated at about 1. Professors Light and Lexchin reported in , however, that the rate of approval for new drugs has been a relatively stable average rate of 15 to 25 for decades. Because of the very long time needed for discovery, development, and approval of pharmaceuticals, these costs can accumulate to nearly half the total expense. A direct consequence within the pharmaceutical industry value chain is that major pharmaceutical multinationals tend to increasingly outsource risks related to fundamental research, which somewhat reshapes the industry ecosystem with biotechnology companies playing an increasingly important role, and overall strategies being redefined accordingly.

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Chapter 8 : Pharmaceutical industry | European Medicines Agency

Key Stakeholders and the effect of their actions on the Financial Sustainability of the Pharmaceutical Company 1. Key Stakeholders and the effect of their actions on the Financial Sustainability of the Pharmaceutical CompanyGroup A1.

Share via Email A former federal health department secretary, Stephen Duckett, says the influence of the pharmaceutical industry contributes to high drug prices in Australia. About 72 separate pharmaceutical businesses engage paid lobbyists to influence government decisions and policy. They are represented by 29 separate lobbying firms, many of which have former ministerial or political advisers as staff. Quick guide Political lobbying in Australia: Lobbyists attempt to influence government policy or decisions on behalf of either a client or their own organisation. Ethical lobbying is a valuable and important element of a healthy democracy. It helps those who have a stake in government policy to convey their views and expertise. There are two broad types of lobbyists: For many Australians, lobbying conjures images of powerful corporations working to sway politicians behind the scenes. There is a truth in that. The big banks, mining and energy giants, pharmaceutical companies, casinos, Amazon, Google and Facebook all engage lobbyists. But lobbyists also work on behalf of not-for-profits and community groups, including for veterans, social workers, aged-care staff, school principals and environmental organisations. What is the lobbyist register? The register was a huge step forward when it was introduced in , but remains frustratingly opaque. Compare that with the ACT, where lobbyists are required to file quarterly reports on their activities, or NSW, where ministers are required to publish their diaries. The federal register is also completely blind to the activities of in-house lobbyists. What is the lobbyist code of conduct? The code tells lobbyists how they must behave when approaching the government and is designed to maintain ethical standards. But the code is not legislated and has no real teeth. It goes largely unenforced and the punishments are weak. The worst sanction available to authorities is removing a lobbyist from the register. The US and Canada have fines or jail terms for law breaches. Who keeps an eye on lobbyists? It takes on a largely administrative role, rather than an investigative or regulatory one. It lacks independence, relies on reports of bad lobbying and rarely, if ever, takes enforcement action. Thank you for your feedback. Twenty-two of the 72 companies that engage lobbyists have also made political donations in the past 19 years. Donations peaked in the financial year, which coincided with the federal election. He said the influence of the pharmaceutical industry clearly contributed to high drug prices. We have policies that are designed to suit them rather than to suit the consumer or taxpayer. In one example industry lobby groups were in the room as the federal government developed its therapeutic pricing policy, a policy aimed at stopping the government wasting money on over-priced drugs. Read more A spokesman for the health minister, Greg Hunt, completely rejected any suggestion that the pharmaceutical lobby had influence over the listing of medicines on the pharmaceutical benefits scheme, a process which he said was completely separate from government. The committee is independent of government by law and in practice. A University of Sydney research scientist, Barbara Mintzes, an expert in pharmaceutical policy, said there had been a global trend towards weakening evidence standards for new medicines. The changes had broadly made it easier for new drugs to get on to the market.