DOWNLOAD PDF REFORMING THE FDA

Chapter 1 : Scott Gottlieb and Reforming the FDA | FreedomWorks

Changing Our Minds: Reforming the FDA Medical Device Reclassification Process. Spenser F. Powell. ABSTRACT. The United States Food and Drug Administration's (FDA) initial classification decision regarding a medical device has an enormous impact on the cost and time requiredâ€"both for the manufacturer and FDAâ€"before the device may enter the market.

Harm reduction Harm reduction refers to a range of public health policies designed to reduce the harmful consequences associated with recreational drug use and other high risk activities. Harm reduction is put forward as a useful perspective alongside the more conventional approaches of demand and supply reduction. Drug liberalization Drug decriminalization calls for reduced control and penalties compared to existing laws. Proponents of drug decriminalization generally support the use of fines or other punishments to replace prison terms, and often propose systems whereby illegal drug users who are caught would be fined, but would not receive a permanent criminal record as a result. A central feature of drug decriminalization is the concept of harm reduction. Drug decriminalization is in some ways an intermediate between prohibition and legalization, and has been criticized as being "the worst of both worlds", [14] in that drug sales would still be illegal, thus perpetuating the problems associated with leaving production and distribution of drugs to the criminal underworld, while also failing to discourage illegal drug use by removing the criminal penalties that might otherwise cause some people to choose not to use drugs. Portugal was the first country in the world that has decriminalized the use of all drugs. This generally means anyone caught with any type of drug, if it classifies as being for personal consumption rather than sale, will not be imprisoned. However, Mexico City has decriminalized certain drugs and Greece has just announced that it is going to do so. Spain has also followed the Portugal model. Italy after waiting 10 years to see the result of the Portugal model, which Portugal deemed a success, has since recently followed suit. In the Netherlands these cafes are called "coffee shops" [18] Legalization[edit] Drug legalization calls for the end of government-enforced prohibition on the distribution or sale and personal use of specified or all currently banned drugs. Proposed ideas range from full legalization which would completely remove all forms of government control, to various forms of regulated legalization, where drugs would be legally available, but under a system of government control which might mean for instance: The regulated legalization system would probably have a range of restrictions for different drugs, depending on their perceived risk, so while some drugs would be sold over the counter in pharmacies or other licensed establishments, drugs with greater risks of harm might only be available for sale on licensed premises where use could be monitored and emergency medical care made available. Examples of drugs with different levels of regulated distribution in most countries include: Full legalization is often proposed by groups such as libertarians who object to drug laws on moral grounds, while regulated legalization is suggested by groups such as Law Enforcement Against Prohibition who object to the drug laws on the grounds that they fail to achieve their stated aims and instead greatly worsen the problems associated with use of prohibited drugs, but who acknowledge that there are harms associated with currently prohibited drugs which need to be minimized. Not all proponents of drug re-legalization necessarily share a common ethical framework, and people may adopt this viewpoint for a variety of reasons. In particular, favoring drug re-legalization does not imply approval of drug use. Decriminalization and legalisation is also supported by rationalists, who also support free adult access to all plants that grow in the earth as an essential human right, currently being denied by most governments. The group does not support the decriminalisation of illegal drugs. Since , the Council has called for the licensing of poppy cultivation in Afghanistan in order to manufacture poppy-based medicines, such as morphine and codeine, and to combat poverty in rural communities, breaking ties with the illicit drugs trade. The Senlis Council outlined proposals for the implementation of a village based poppy for medicine project and calls for a pilot project for Afghan morphine at the next planting season.

Chapter 2 : Learning from Prozac: A Case Study on Reforming the FDA Drug Approval Process

Without a doubt, one of the most important American regulatory bodies is the FDA. As the agency charged with ensuring the safety of everything from the protein shake you drank after the gym to the.

This bipartisan legislation reauthorizes and reforms user fee programs for drugs and medical devices. What are user fee programs? The Food and Drug Administration reviews new pharmaceuticals and medical devices to make sure that they are safe and effective. FDA works with these industries to negotiate a fee that will help pay for government review personnel. Every five years the fees are renegotiated and the legislation authorizing these programs is renewed. This legislation is critical to our medical innovation economy. In Pennsylvania, over 37, work in the pharmaceutical industry and over 22, work in the medical device industry. Without timely review of new products, many of these jobs would be at risk. Over the last year and a half, the Health Subcommittee has held 10 hearings to investigate aspects of the review system and prepare the FDA Reform Act. Early on, we discovered problems with the review of medical devices. In a hearing last year, we heard from investors and venture capitalists that the review of devices had become a barrier to investment in the U. We also heard firsthand from companies struggling to work with the FDA. Last fall, I became aware of the difficulties facing one small Pennsylvania company, Philadelphia-based InfraScan. The company created a non-invasive device to help detect brain injury. A normal human brain will absorb light evenly. If there is bleeding, the absorption level will be different. In just a few short minutes, the device can warn medical professionals that an injury is serious and that the patient should be rushed to a hospital. This device was developed specifically with the U. While the device was approved in Europe in 30 days, it took nearly four years for the FDA to give their assent. Investors warned us that the difficulty of the review process is making them think twice about putting money into U. Venture capitalists are looking to put more money into European companies. Also, some American companies are thinking about relocating facilities to countries where they could actually market their products. The FDA Reform Act will help us turn back that tide by making the review process more transparent, more consistent, and more predictable. From the beginning, I worked with my Democratic counterparts on the Energy and Commerce Committee to put together legislation we could all agree on. During the Health Subcommittee consideration of the bill, every member who spoke was grateful for the bipartisan work. However, at the end of the day we compromised to move this legislation forward in a timely manner. The current law authorizing FDA user fee programs expires later this year. The full House of Representatives could vote on our legislation in the coming weeks. Meanwhile, the Senate is working on its own version of the bill. Work in the other chamber has also been bipartisan. American companies are working on incredible new devices and drugs to help patients.

Chapter 3 : Would reforming the U.S. patent system help to lower drug prices? - STAT

Reform FDA Campaign Overview The corrupt governmental agency that says it's "protecting and promoting your health" is directly responsible for the deaths of 50, Americans each year. We believe that the FDA is a broken agency that needs a complete reform and restructuring.

Please enter a valid email address. August 11, at 1: Consider the exorbitant pricing of prescription pharmaceuticals. The central issue concerns statutory i. Meant to incentivize pharmaceutical companies to do the financially risky work of developing new drugs, it perversely encourages these companies to plunder for profit while the getting is good. Below are my suggestions for how patients can get a fair deal. My solutions would maintain the pace of innovation while opening the bathroom cabinet to free-market competition, driving down costs for patients. Statutory Exclusivity The U. While it was intended to reward innovation while encouraging cheaper generics, it has instead led to price gouging. Currently, if a pharmaceutical company develops a new drug or reformulates an older drug for a new indication, the FDA grants it three-to-five years of market exclusivity. This means no other company is permitted the sell the drug during this period, regardless of the validity of patents held by the innovator. Taking advantage of this monopoly, pharmaceutical companies are compelled to price new drugs at outrageous premiumsâ€”typically, more than 20 times sometimes as much as X the cost of manufacturing the drug. After the statutory period of exclusivity, the ability of the pharmaceutical company to fend off rivals, meaning inexpensive generics, becomes a dog fight over patent protection. The outcome of litigation in the U. Patent and Trademark Office and the circuit courts is extremely unpredictable. When generics enter the market, typically priced at just 2X their manufacturing cost, patients pay dramatically less. I have a suggestion for fixing this system: As part of audited financial statements, the cost of goods is already a line item. To further reward the pharmaceutical companies, I would propose extending the period of statutory exclusivity up to 12 years. This is the same period of statutory exclusivity now enjoyed by new biologics. Those biologic products should also be required to limit their pricing to a 10X multiple of costs. After 12 years, if a pharmaceutical company wants to duke it out with a generic-drug manufacturer over any remaining patent protection, so be it. As patients, we get affordable innovations. For the pharmaceutical innovators, they get an assured, extended period of exclusivity with very good margins and a great rate of return for their investors over a guaranteed twelve year period. The pharma companies no longer need to price exorbitantly in order to be sure that their investors will be rewarded during a limited period of exclusivity.

Chapter 4 : Drug policy reform - Wikipedia

Incentives matter, brainpower matters, and incentives and brainpower interact in unpredictable ways. It follows that the worst way to organize weather forecasting â€" the way to ensure inferior.

The drug posted record sales and attracted unprecedented public attention. First, Prozac caused none of the uncomfortable side effects, such as dry mouth, blurred vision, racing heartbeat, constipation, cognitive impairment and weight gain, that were associated with older antidepressants and that discouraged patients from continuing with those medications. A second major advantage of Prozac was the inability of a patient to use the drug to commit suicide. Responding to the record sales and the significant advancement in the treatment of depression, the media began to flaunt the virtues of Prozac. New York Magazine73 and Newsweek74 both extolled the virtues of Prozac and stories began to emerge of patients, previously "incurable," for whom Prozac had worked a miracle. See infra, note Rosenbaum, supra note 60 citing F. Cowley, supra note No other treatment had relieved her suffering; however, within a month of taking continued The study said that each of the six patients developed obsessively intense thoughts of suicidal and violent behavior that abated only after discontinuation of Prozac. The media had picked up the story of problems associated with Prozac. Id Other stories reported in the media describe similar "miraculous" cures. The study provided only anecdotal evidence of the experience of these six patients and did not draw the specific conclusion of a causal link between Prozac and violence. Wesbecker, who was being treated with Prozac, opened fire with an AK at his workplace, shooting twenty of his co-workers and killing nine, including himseW in September Y Three widows of the eight workers killed filed suit Allen G. That increase represents an average of The story is detailed in many of the media reports on Prozac in late and and varies slightly in some of the minor details. Vale, The Rise and Fall of Prozac: A third week of advertisements promoted the Church and included glossy inserts critical of Lilly. Id 87 Id 88 Rosenbaum, supra note 60, at As an example of this phenomenon, Dr. Rosenbaum reprinted the following letter received by a colleague: I watched the Joan Rivers show yesterday and even though you had given me the paper explaining those negative things about Prozac, this program really gave me second thoughts. I will just try harder to get myself together, to get to more Al-Anon meetings and hope for the best. I have limited medical coverage and I came to you with sincere hopes. Thank you for considering me, sorry for any inconvenience. The letter shows the problem inherent in the negative publicity. The expense of choosing to go without treatment, however, will be either continuing to live a life of diminished quality blunted by depression or ultimately becoming one of the ten percent or more of depressed patients who commit suicide. Following a public hearing and consideration of scientific evidence on September 20, , the Committee recommended remaining on the course the FDA had been following: Id 96 Supra, note Peter Kramer, an associate clinical professor of psychiatry at Brown University and private practitioner in Providence, who published Listening to Prozac. Describing this phenomenon, Dr. Kramer wrote that Prozac appeared to "[give] social confidence to the habitually timid, [make] the sensitive brash, [lend] the introvert the social skills of a salesman. Prozac was transformative for patients in the way an inspirational minister or high-pressure group therapy can be Without directly tying the increased use of Prozac to the publication of Dr. Another reporter described the book as "another makeover" for the drug, increasing its popularity among Americans. Miller, Listening to Eli Lilly: The Church had not abandoned its campaign against Lilly and Prozac. Moreover, evidence was beginning to mount that the drug caused some serious side effects and interactions for a significant number of patients using Prozac. See infra, notes and accompanying text analyzing the FDA approval process for Prozac. The original marketing information continued Though known to occur in some patients using antidepressants, the serotonin syndrome was becoming more common as the use of SSRls was becoming more widespread. The problem with this information is that sexual dysfunction can lead to noncompliance with drug therapy. Physicians would not necessarily focus on Prozac use as a source of sexual dysfunction when the marketing information estimated its incidence at such a low rate. This was first documented in Kramer, supra note 97 describing many of his patients who underwent personality changes after beginning to use Prozac. In Texas, consumer advocates

began to seek state remedies to require the labeling information that the FDA would not authorize. By petitioning to require pharmacists to attach labels to bottles used in dispensing the prescription, the group would skirt the issue of federal pre-emption over prescription drug labeling, because the practice of pharmacy is regulated by state law. These trends were problematic because of the developing evidence on side effects, primarily the potentially fatal serotonin syndrome. By prescribing Prozac to patients who really did not need it and by leaving patients on the drug indefinitely, physicians exposed their patients to the risk that their brains would build up too much serotonin and they would, essentially, overdose on serotonin. Also, studies began to show that Prozac carried with it the same failure Id internal quotation marks omitted. Nonspecialists in this situation fail to determine if all the symptoms that should be present before drug therapy is started are present for the patient about to receive the prescription. As a result, consumers would continue to provide mixed signals regarding their acceptance of Pro zac, because there now were legitimate dangers associated with it. In promoting these trends, physicians ignored the effect that the public has on the approval and marketing process and helped to increase the costs associated with the controversy. On the one hand, Lilly defended Prozac against the data collected on sexual dysfimction, saying that sex difficulties will almost always be under-reported in clinical trials; challenged accounts such as Dr. It also seems likely that any study of a drug will tend to underestimate the incidence of sexual dysfunction because of the delicacy of exploring the issue with clinical test subjects. Once a drug has been approved for marketing, the sponsor may only market the drug for the indication listed on the original NDA. To market the same drug for use in treating other illnesses, the sponsor must obtain an approval from the FDA, indicating that the drug is safe and effective for the treatment of the other condition or conditions. See Walsh and Pyrich, supra note 1, at outlining the process for obtaining approval for a supplemental indication and concluding that "because of the cost in both time and money involved, manuThcturers are reluctant to submit [applications for supplemental approval] for their products". The personal cost for the depressed individual and his or her family would be "difficult to measure, though an important indicator is the more than 15 percent of depressed people who commit suicide and the more who come close. For a moving account of the personal and social costs of depression, see id at Eli Lilly and Company , F. Currently, though, no judgments have been entered against Lilly and the litigation continues to make its way through procedural issues. Products liability suits placed an additional tax on the company who, in good faith, had already expended vast resources to provide a drug to the public that the public, through its political process, had judged to be beneficial in the treatment of depression. The greatest cost came in the losses sustained as patients in need of treatment did not receive, either because of their fear of the drug induced by negative hype or because hysteria had trivialized their illness, a safe medication that could be effective for them. The Drug Approval Process for Prozac Reviewing the process that Prozac underwent to obtain FDA approval for marketing shows that the process was deficient in several respects. SBA, supra note , at I. The SBA notes that therapy for depression can require treatment for longer than four weeks, as acute episodes of depression normally respond only after several months of treatment. Id Antidepressant treatment for months-long periods of time is generally accepted as a standard treatment regimen for depression. Delgado and Alan J. Gelenberg, Decision Making in the Use of Antidepressants. At the end of three to four weeks, antidepressants will usually have had some effect on the patient, but the patient will generally not experience the fill therapeutic effect of an antidepressant until week twelve of the drug therapy. If significant amelioration of depression is a demonstable [sic] effect of this drug, this benefit would appear to outweigh any potential risks associated with its clinical use which became evident among patients exposed to fluoxetine reported in this NDA". See infra, note explaining the importance of this finding of safety in overdose as it relates to depressed patients. MAO-inhibitors are antidepressants that are frequently associated with dangerous interactions with certain foods and medications. Wolman and George Stricker eds. The list of substances to avoid ranges from alcohol, cheese, certain meats, and beans to cold and allergy medicines, appetite suppressants, and other antidepressants. Thus, a determination of possible interaction with MAO-inhibitors was critical to the finding of safety. Id The pooled population of fluoxetine-exposed test subjects had 6, patients. See SBA, supra note , at SBA, supra note , at The other 36 patients recovered without any lasting effects. Thus, it is never the case that a drug has received a thorough review of the long-term effects associated

with continuous use. See infra, note and accompanying text. Of these patients, only had received fluoxetine for more than days and only 74 of the had received fluoxetine for more than days. Because physicians could prescribe fluoxetine to their depressed patients without fear that the drug would accomplish a suicide attempt, as was true with older antidepressants, delaying the availability of fluoxetine could compromise the safety of patients already receiving antidepressant drug therapy. Of the 6, test subjects in the pooled safety sample, only six percent of the population had received the drug for more than one year. It is generally agreed among expert psychopharmacologists circa that acute episodes of depression require several months or longer of sustained pharmacologic therapy". See also, supra, note The potential for suicide in depressed patients is great: Thus, any medication that will continued Because Lilly had given no indication of the methods used to collect the data on adverse effects, the clinical data review concluded that there was no systematic procedure in place and that the reporting of adverse effects was left to the discretion of the clinical investigators; in addition, Lilly instructed investigators not to include experiences caused by depression. Each investigator would have had his own idea of what depressive experiences might comprise resulting in a lack of generalizeability [sic] from one investigator to the next. Though the FDA obviously concluded that the The considerations given to safety in reviewing fluoxetine were therefore not irrational, and it could be justifiable for the FDA to conclude that this significant advantage outweighed the risks of having incomplete long-term data. However, there are no data that establish how often the older antidepressants were used to attempt suicide, making it unclear whether this advantage of fluoxetine outweighed the risk of rushing the drug to market based on clinical test data derived from trials of inadequate duration. Besides spontaneous reporting, Lilly could have instructed researchers to conduct systematic interviews designed to elicit adverse effect reports. Instead, Lilly instructed investigators to record all patient experiences on the drug and to make a determination as to the causation of the experience. Lilly provided no parameters or criteria for making that determination. Thus, if the FDA will incur this responsibility, then the FDA also has the responsibility to ensure that information on adverse effects is as complete as possible. With such skewed information on the adverse effects associated with fluoxetine, there was no clear indication of what the adverse effects of fluoxetine use were likely to be.

Chapter 5 : Reforming the FDA's Drug Approval Process Medical Education on ReachMD

An FDA inspector checks the cleanliness of a compounding tank at a Baltimore drug plant. (Photo Credit: Food and Drug Administration) The Food and Drug Administration rarely has a shortage of critics.

We believe that the FDA is a broken agency that needs a complete reform and restructuring. The drugs the FDA approves are so dangerous that they kill 50, Americans and send more than , more to emergency rooms each year. A hormone replacement drug has been repeatedly linked to breast cancerâ€”not only increasing the risk of cancer, but also making it more likely that the cancer will advance quickly and prove fatal. Yet FDA has taken no action whatsoever to remove it from the market. FDA protects entrenched medical monopolies which pay its bills and hire its employees. Not only that, it is commonplace for former FDA employees to find work with major drug companies. An FDA-approved therapy has been linked to jawbone deterioration, jaw death, and potential esophageal cancer. An FDA advisory committee now wants the FDA to limit how long a patient may be on bisphosphonate therapy, but committee members cannot agree on an appropriate time limit. The FDA recently released new guidelines that were supposed to guide supplement manufacturers in how to give notification that they were introducing a new dietary ingredient. Instead, they gave a big, fat gift to the pharmaceutical industry â€”if implemented, the guidelines would force most supplements off the shelves and would drastically raise the price of the ones that remain, contrary to congressional intent. The agency is also waging war against raw milk. Raw milk has shown to be superior to pasteurized milk in protecting against infection, diarrhea, rickets, tooth decay, and tuberculosis; children drinking raw milk have better growth rates than those drinking pasteurized milk. The FDA restricts free speech about nutritional supplements and natural products, and censors the communication of legitimate, peer-reviewed scientific research. Research from Harvard suggested that cherries could reduce the risk of heart attack, but FDA did not allow cherry producers, sellers, or manufacturers to talk about that research, and sent a cease-and-desist letter to twenty-nine companies telling them to stop making claims about these health benefits or face fines and jail! The agency forced them to sign a consent decree promising not to share the scientific findings and pushed them to the brink of bankruptcy, all because their websites contained links to the Harvard cherry research. As you can see, the FDA has essentially become a hired gun for the pharmaceutical industry. These failures affect the health of all Americans. The agency obstructs medical science and innovation. Good drugs are either not approved or are approved after interminable delays. Even after new drugs are shown to be safe, doctors are not allowed to use them with terminally ill patients whose cases are otherwise hopeless. Instead, the FDA approves a shocking number of extremely dangerous and often addictive drugsâ€”often on the basis of a recommendation by panels whose members include consultants from drug companies that have deliberately suppressed unfavorable scientific drug studies. What is needed is not incremental reform but complete reform, a thorough overhaul of every part of the FDA. The purpose of our Reform FDA campaign is to persuade the American public and Congress that a total reform of the FDA is absolutely necessary in order to rebuild the American healthcare system and make it once again the envy of the world. We must persuade Congress to address the comprehensive failure of the FDA. We must collect such a large number of names on the petition that it compels congressional action. We will hand-deliver the petition to congressional leaders and urge them to enact comprehensive FDA reform. Congress already knows that the FDA has serious problems. This petition will help move them to take the urgent action required.

Chapter 6 : Reforming the FDA: CQR

Get this from a library! Reforming the FDA. [Richard L Worsnop] -- The Food and Drug Administration rarely has a shortage of critics. That's not surprising considering the agency's extraordinary role in American life: 25 cents of every consumer dollar is spent on.

Chapter 7 : Reforming the Drug Compounding Regulatory Framework - Energy and Commerce Committee

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Rep. Joe Pitts Pottstown Mercury Earlier this month, the Health Subcommittee and the full Energy and Commerce Committee approved the Food and Drug Administration Reform Act of

Chapter 8 : Reforming The FDA - Republican Party of Pennsylvania

In an important editorial in Science, Andy Grove, former Chief Executive Officer of Intel Corporation, advocates restricting the FDA to safety-only trials. Instead of FDA required efficacy trials patients would be tracked using a very large, open database. The biomedical industry spends over $

Chapter 9 : Proposed Legislation to Reform the OTC Drug Monograph System

It takes a substantial measure of time, money and manpower to bring a new drug from the bench to the marketplace. One key aspect of this sequence is the drug approval process, overseen by the Food and Drug Administration (FDA).