STRING IMPLANT PHYSICIANS

Re: I think somebody needs to get a hearing aide ... (http://forum.bearchive.com/index.php?topic=40100.msg41369#msg41369)
« **Reply #45 on:** September 09, 2002, 02:53:20 AM »

(http://forum.bearchive.com/index.php?action=profile;u=585)

Lesbian Bob (http://forum.bearchive.com/index.php?action=profile;u=585)

F Cup

875

In 1994, Congress further limited the FDA's authority to regulate food supplements, and this led to an increase in the promotion of those "all natural" products (and some not really natural, like ephedrine) that do nothing but empty people's wallets. All in the name of reducing government interference in our lives, of course, not out of scientific ignorance or bribery.

If Congress had never previously limited the power of an agency, where is the Interstate Commerce Commission now?

A junk drug is almost anything sold in tiny bottles in health food stores. The companies that produce them don't remotely do as much research as the legitimate drug makers do.

Logged

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41395#msg41395)
« **Reply #46 on:** September 09, 2002, 06:06:28 AM »

(http://forum.bearchive.com/index.php?action=profile;u=769)

Connoisseur (http://forum.bearchive.com/index.php?action=profile;u=769)

E Cup

> In reply to:
>
> That "evidence" link is for a not-so-credible study by economists, not scientists, and its conclusion is just a little

343

too neat and tidy to be believable without a lot more evidence.

Firstly, economists are better equipped to perform such analyses than are scientists in that economist are accustomed to doing so. Unlike scientists, they don't have the luxury of being able to perform experiments, so they've become skilled at making rigorous inferences from real-world data. Moreover, we'll never have the concrete evidence of the concrete sort that you appear to want because we're dealing with a conterfactual – what would have happened if the FDA didn't exist. [So it's not as simple as exposing mice to gamma rays, noticing that 50 times as many died as in the control group, and then concluding that gamma rays are harmful to mice].

Secondly, that a conclusion is "neat and tidy" is hardly an effective critique. After all, our major scientific theories are all neat and tidy. Should we dismiss them as well? I know it's time consuming, but you actually have read and understand the arguments in order find any errors in them.

> In reply to:
>
> That think tank makes another incredible claim, that law enforcement in 19th century Britain was highly effective, but Britain was known as the crime capital of Europe back then.

The claim that 19th-century British law enforcement was highly effective is hardly "incredible". 19th-century British crime rates were quite low, especially by modern standards. See *Guns and Violence: The English Experience* (http://www.amazon.com/exec/obidos/ASIN/0674007530/qid%3D1028518854/2/ref%3Dsr%5F1%5F2/102-5179268-6300156), which is summarized here (http://www.foxnews.com/story/0,2933,59866,00.html). [Perhaps you're thinking of late medieval and early modern Britain.]

> In reply to:
>
> Do you have any evidence by credible scientists that the FDA does more harm than good?

Here's a piece (http://healthfactsandfears.com/featured_articles/jun2002/regulation061802.h by a Dr. Henry Miller, who was an official at the FDA between 1979 and 1994. Although he believes that the FDA is killing lots of people, he doesn't compare the deaths to any estimates of lives saved. [With regard to finding whistle blower scientists, keep in mind that scientists need to eat just like the rest of us. They're not particularly interested in biting or even criticizing the hand that feeds them, especially if it means a reduced chance at landing jobs, being promoted, or getting their grants renewed.]

It's *my* opinion (shared by the authors of the analysis that I cited) that the FDA does more harm than good. My reason's are 1) That you wouldn't have Hell on earth in the absence of an FDA, as long as you've got a functioning system of torts, a free market, a free press, and a population of average intelligence. So the FDA's benefit (if any) is on the margins. 2) The well known job-preserving, responsibility-avoiding behavior of bureaucrats. 3) The contrafactual arguments of the type that I cited.

Am *I* a credible scientist? Well, I do have Ph.D. in a theoretical branch of physics. So I'm familiar with subtle quantitative reasoning. Obviously, I

don't expect that to convince you of anything. All I can say is that your belief about the FDA is completely reasonable -- until you look into it. It's just how I used to think. I know that it's difficult to come to conclude that an agency that we've trusted to protect us, is actually harming us. But I think that if you study the matter, this is the conclusion that you'll reach. Unless you're some sort of genius, it will take you a while to suppress any biases, and fully digest the arguments and data. But you'll get there.

Now if I seem like a total moron who's completely full of it, please feel free to dismiss the notion of the FDA being on balance detrimental.
Otherwise, take the trouble to seriously consider the idea by looking into it.

Homework Assignment:
If an FDA-like agency was able to ban computer software (on the grounds of not being safe or effective). Would we be
a) better off
b) worse off
c) the same as now

Now let's get back to talking about huge tits.

Logged

(http://forum.bearchive.com/index.php?action=profile;u=860)

melonie_charm (http://forum.bearchive.com/index.php?action=profile;u=860)

G Cup

1147

(www.meloniecharm.com)

Re: String Implants - 'you can't handle the truth' again (http://forum.bearchive.com/index.php?topic=40100.msg41429#msg41429)
« **Reply #47 on:** September 09, 2002, 07:49:03 PM »

OK, let's quit beating around the bush. On one side we have thousands of established plastic surgeons exchanging pleasantries with fellow 'Board' members, and getting good deals from the two major US implant makers. The implant companies are selling small silicone rubber implant bags to the doctors for $1000+ a pair, and the doctors are reselling those to their patients for $1500+ a pair. Now along comes five or ten dollars worth of Prolene suture string to take their place 🤔

Logged

Breast Expansion Archive Forum

Re: String Implants - 'you can't handle the truth' again (http://forum.bearchive.com/index.php?topic=40100.msg41429#msg41429)
« **Reply #47 on:** September 09, 2002, 07:49:03 PM »

(http://www.cashforge.com/banners/dz32ffu9bsb:520)

Re: String Implants - 'you can't handle the truth' again (http://forum.bearchive.com/index.php?topic=40100.msg41437#msg41437)
« **Reply #48 on:** September 09, 2002, 08:28:46 PM »

(http://forum.bearchive.com/index.php?action=profile;u=1833)

ninjrk (http://forum.bearchive.com/index.php?action=profile;u=1833)

F Cup

685

Yeep. With all due respect, an 18 inch length of Prolene costs ~$4. It will fill 0.5 cc's. Did a volume test with 3-0 Prolene in surgery today. I'm assuming that the discount in bulk will lower this to a 1/4 of that, or $1. So let's say $2 a cc. Heck, let's cut that to $1 a cc. That's $500 for a 500 cc implant. It might be a bit cheaper, but it's not a lot cheaper than classic implants. More importantly, at least a few models are having significant seromas develop continually around the implant that require drainage. Poke a hole in a seroma and it's now called an abscess. A normal implant will be surrounded by fibrous tissue and then the reaction tapers off to a very low level. That's not happening here. It's great for the model's career, I'm sure. Look how big so-and-so is this week. Went though Pubmed today and dredged up some literature on Prolene reactions and there are allergic reactions to it after attempted reaction. It's rare, fortunately, but developing an allergy to one's implant might be. . . unpleasant. That's implant rejection a few levels further.

The real problem is the cost of the implants. The few manufacturers can take in huge profits because there are few that find it worthwhile to go through the extensive testing required, so they can charge exorbitant prices for these implants. For heaven's sake, I can buy a robust 1000 mL silastic bag of saline for $4. The only difference is the shape and binding method. Problem is, the FDA got hammered politically and monetarily during the silicone breast implant BS, so they have made cosmetic implants very hard to certify, so that they can never again be crucified for not doing their job. Sucks, but there you go.

Matt

Logged

Be nice to everyone you meet, but have a plan to kill them if you have to.

"the only thing unnatural about my tits is how fucking amazing they are!" LOL

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41440#msg41440)

« **Reply #49 on:** September 09, 2002, 09:01:56 PM »

(http://forum.bearchive.com/index.php?action=profile;u=1833)

ninjrk (http://forum.bearchive.com/index.php?action=profile;u=1833)

F Cup

685

>Do you have any evidence by credible scientists that the >FDA does more harm than good?

>Here's a piece by a Dr. Henry Miller, who was an official >at the FDA between 1979 and 1994. Although he believes >that the FDA is killing lots of people, he doesn't compare >the deaths to any estimates of lives saved. [With regard >to finding whistle blower scientists, keep in mind that >scientists need to eat just like the rest of us. They're >not particularly interested in biting or even criticizing >the hand that feeds them, especially if it means a reduced >chance at landing jobs, being promoted, or getting their >grants renewed.]

I respect the heck out of Dr. Miller, I've heard him speak several times. I also agree with many of his beliefs, mainly that the FDA is in need of reform. It does a good job, but not a great job. That said, note that he doesn't advocate getting rid of the FDA. Rather, he wants it to be a governing body for a system of independent testing bodies. So, we do much the same testing, but presumably free-market forces keep the prices down. This, I am less sure of. First off, who says that all testers will be equal? CRO's (that do some of the early stage pharmaceutical testing) aren't and ther are some that have the quiet reputation of having more favorable study results than others. Is it a possibility that pharmaceuticals will lean towards those less stringent companies? Oh yeah. Second, he cites the European device manufacturers. Interesting, since I deal with many of their CV devices and, to be blunt, many that pass through that process suck. Poor molding, bad adhesions, pitted surfaces, etc. They have a significantly higher failure rate. Also, there is one thing that the EU companies don't have to deal with that we do, trial lawyers

that the EU companies don't have to deal with that we do, that lawyers. Nowadays, since it's the pharmaceutical company overseeing the testing, they are the ones that get sued. A 9 billion dollar company can get good lawyers. A 25 million dollar testing company is not in that kind of shape. In addition, the pharmas can point to the FDA and claim independent verification, something that is difficult to challenge without a true smoking gun.

>It's my opinion (shared by the authors of the analysis >that I cited) that the FDA does more harm than good. My >reason's are 1) That you wouldn't have Hell on earth in >the absence of an FDA, as long as you've got a functioning >system of torts, a free market, a free press, and a >population of average intelligence.

Umm, did you watch the silicone implant debacle? The free press sold the sensational story, the women voted with their feet, and the population believed that they were death incarnate. Heck, the free press gives glowing stories to BS treatments, watch 20/20 half the time when they talk about cancer. 60 minutes on a guy whose cancer went into remission after he gargled yak urine. Never mind the 100 who died.

>So the FDA's benefit (if any) is on the margins. 2) The >well known job-preserving, responsibility-avoiding >behavior of bureaucrats. 3) The contrafactual arguments of >the type that I cited.

We can regulate one way or the other. Either more drugs are released without current standards of testing, some will be heaven on earth, some will kill lots of people. Or, we err on the side of releasing only heavily tested drugs with some viable therapies never being developed but few dangerous treatments released. Note that every once in awhile a fully tested drug is found to kill a dozen or so of the 1000's of people taking it. It is huge news. That's out of a few thousand drugs a year. It's so rare that when a dozen people die it is huge news. What would that ratio be without the testing?

>Am I a credible scientist? Well, I do have Ph.D. in a >theoretical branch of

physics. So I'm familiar with subtle >quantitative reasoning. Obviously, I don't expect that to >convince you of anything. All I can say is that your >belief about the FDA is completely reasonable -- until you >look into it. It's just how I used to think.

Sorry, it's still reasonable. They could use many procedural improvements. But all of the debates from people like Dr. Miller say to keep the same testing, but structure it differently. When I started out, the FDA was the enemy as they slapped down my new wonder devices. I have learned a grudging respect for them over the years. Overall, they do a good job. Someone needs to hold their feet to the fire and make them do a great job.

>Homework Assignment:
>If an FDA-like agency was able to ban computer software
>>(on the grounds of not being safe or effective). Would we >be
>a) better off
>b) worse off
>c) the same as now

Poorly worded argument, since nobody dies of a computer program. How about this:

Homework Assignment:
If an FDA-like agency was able to ban computer software (on the grounds of not being safe or effective) which, if poorly written would cause the computer to explode with the force of 1000 lbs of TNT should we:

a:make sure that all software is tested not to blow up
b:Accept that a few thousand people killed each year by exploding computers was the price of progress

Matt

PS, dog food and its labeling are regulated by the Association of American Feed Control Officials, the department of Agriculture, and (ta da) the FDA

Logged

Be nice to everyone you meet, but have a plan to kill them if you have to.

"the only thing unnatural about my tits is how fucking amazing they are!" LOL

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41450#msg41450)
« **Reply #50 on:** September 09, 2002, 10:13:36 PM »

(http://forum.bearchive.com/index.php?action=profile;u=93)

Morphermor (http://forum.bearchive.com/index.php?action=profile;u=93)

717

(http://bearchive.com/~morphermor/)

PS, dog food and its labeling are regulated by the Association of American Feed Control Officials, the department of Agriculture, and (ta da) the FDA

the fact still remains, that dog food is healthier than Similac...

Logged

Pardon me while I stare...

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41452#msg41452)
« **Reply #51 on:** September 09, 2002, 11:07:03 PM »

(http://forum.bearchive.com/index.php?action=profile;u=1833)

ninjrk (http://forum.bearchive.com/index.php?action=profile;u=1833)

F Cup

685

Different dog foods are healthier than others. More importantly, Similac fullfills a very specific requirement, it acts as a viable substitute to mother's milk during infancy before the immune system is fully developed. The difficulty in coming up with a perfectly rounded nutritive supplement that leads to no allergies and can be given even to a premature baby is rather high. It is, in fact one of a very few breast milk replacements that can be given when the infant is allergic to it's own mother's milk.Try mashing up a can of alpo with some water and see how long a human baby can survive on it.

Lesser tolerences on pet food is acceptable because their GI tracts are a lot more robust than ours. Plus, few will pay $50 for a bag of dog food, so common sense prevails. If a few dogs die because of poor nutrient absorption of a constant case of the runs, c'est la vie. If your son dies in infancy because of a crappy supplement that doesn't mesh with his digestive system, there will be hell to pay.

Matt

Logged

Be nice to everyone you meet, but have a plan to kill them if you have to.

"the only thing unnatural about my tits is how fucking amazing they are!" LOL

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41454#msg41454)
« **Reply #52 on:** September 09, 2002, 11:14:10 PM »

(http://forum.bearchive.com/index.php?action=profile;u=769)

Connoisseur

In reply to:

(http://forum.bearchive.com/index.php?action=profile;u=769)

E Cup

343

> Heck, the free press gives glowing stories to BS treatments, watch 20/20 half the time when they talk about cancer. 60 minutes on a guy whose cancer went into remission after he gargled yak urine. Never mind the 100 who died.

I don't watch *20/20*, but I highly doubt that ABC's legal department would have allowed them to run stories effectively endorsing bogus treatments. We do have a fully functional (if not hyper-functional) system of torts in this country. There's no shortage of lawyers who'd salivate at the thought of being able to sue a whale like Disney on behalf of any victims.

> In reply to:
>
> We can regulate one way or the other. Either more drugs are released without current standards of testing, some will be heaven on earth, some will kill lots of people. Or, we err on the side of releasing only heavily tested drugs with some viable therapies never being developed but few dangerous treatments released. Note that every once in awhile a fully tested drug is found to kill a dozen or so of the 1000's of people taking it. It is huge news. That's out of a few thousand drugs a year. It's so rare that when a dozen people die it is huge news. What would that ratio be without the testing?

This isn't rocket science. All we want to do is choose the policy that maximizes public benefit. While the precise definition of "public benefit" might be a point of controversy, a definition that most would find reasonable is "the minimization of involuntary death and suffering".

Now I don't think anybody is arguing that the FDA is too lax. Rather, the consensus critique of the FDA is that it's too conservative, because, for obvious reasons, it seeks to minimize deaths resulting from its approval decisions. In other words, *its goal is **not** to minimize total death and suffering*, just death and suffering resulting from FDA approved drugs or treatments. Hence, as you've noted, the rarity of such events.

This is heinous behavior. The FDA, in order to protect itself, is knowingly allowing perhaps tens of thousands of needless deaths each year. Remember your high school calculus. Either the FDA's policy is at the minimum point on the graph of Deaths vs. Policy, or it's not. If it's not, people are dying unnecessarily.

> In reply to:
>
> When I started out, the FDA was the enemy as they slapped down my new wonder devices. I have learned a grudging respect for them over the years. Overall, they do a good job.

They do a good job of minimizing death and suffering from FDA approved drugs, additives, and treatments. The point is that *this is the wrong goal*

(unless, of course, you belief that the health of the FDA is more important than that of the public).

> In reply to:
>
> Homework Assignment:
> If an FDA-like agency was able to ban computer software (on the grounds of not being safe or effective) which, if poorly written would cause the computer to explode with the force of 1000 lbs of TNT should we:
>
> a:make sure that all software is tested not to blow up
> b:Accept that a few thousand people killed each year by exploding computers was the price of progress

This example strangely assumes that the software yields no life-saving benefits. Upon eliminating this tacit assumption, it's clear that the correct answer is

c. Allow the software to be released in a way that maximizes public benefit (by minimizing death and suffering).

In other words, a release policy in which a million people are saved for every thousand that are blown to bits is better that a policy that prevents these explosive deaths at the cost of a million silent deaths.

Regarding reform of the FDA vs. abolishing it:

I think that the proper reform is to allow it to merely advise rather than to ban (which some might view as tantamount to abolishment in that the FDA would only be heeded to the degree that its advice is good – i.e. it would have to stand on its own merits rather than rely on the force of arms).

I'd be quite happy, however, if the FDA's powers were reduced to their pre-1962 levels.

Logged

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41461#msg41461)
« **Reply #53 on:** September 10, 2002, 12:36:46 AM »

(http://forum.bearchive.com/index.php?action=profile;u=585)

Scientists can analyze data as well as economists can because they frequently have to prove that their test results aren't within the margin of error

Lesbian Bob
(http://forum.bearchive.com/index.php?action=profile;u=585)

F Cup

875

effort.

Economists are famous for neat & tidy conclusions based on scant evidence, such as claiming that drivers of cars with antilock brakes crash more by almost exactly the number of accidents prevented by antilock brakes. In other studies economists and sociologists have made similar conclusions about guns and air bags, and it seems that the politically biased press has taken such studies much more seriously than scientists have.

The effectiveness of FDA regulation could be tested by comparing other countries where medical regulation is similar or different and by adjusting for factors like standard of living and level and type of doctors' training.

Could you cite some countries where medical care is better because of less government regulation, once factors like like diet, level of insurance coverage, standard of living, and smoking are considered?

Logged

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41498#msg41498)
« **Reply #54 on:** September 10, 2002, 05:42:15 AM »

(http://forum.bearchive.com/index.php?action=profile;u=769)

Connoisseur
(http://forum.bearchive.com/index.php?action=profile;u=769)

E Cup

343

> In reply to:
>
> Could you cite some countries where medical care is better because of less government regulation, once factors like like diet, level of insurance coverage, standard of living, and smoking are considered?

As your question implies, making international comparisons is complicated by having to adjust for other differences between countries that might affect the results.

That's why I prefer looking at differences over time within the same country. For example, we can compare the U.S. before and after 1962, when FDA's powers were increased (no time limit on approval decisions).

If we confine our attention to the effect of the increased approval time that occurred after 1962, we can quantify the number of deaths caused by this new delay.

This increased delay would have been justified had people been dropping like flies due to approved drugs pre-1962. But they weren't. The worst pre-1962 tragedy in the U.S. was that caused by "Elixir of Sulfanilamide" (essentially antifreeze) that killed 107 people in 1937. More people (thousands) are killed annually by the increased delays.

The point is that this sort of analysis is far simpler and therefore more persuasive than an international comparison in which you have to control for differences in legal, cultural, social, economic and dietary variables.

Logged

(http://forum.bearchive.com/index.php?action=profile;u=2010)

tndvrs (http://forum.bearchive.com/index.php?action=profile;u=2010)

L Cup

2079

(http://removed I O Wrong content)

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41503#msg41503)
« **Reply #55 on:** September 10, 2002, 06:18:17 AM »

morphermor
PS, dog food and its labeling are regulated by the Association of American Feed Control Officials, the department of Agriculture, and (ta da) the FDA

the fact still remains, that dog food is healthier than Similac...

Woef? woef!

Logged

who am I.....
http://www.bearchive.com/~tndvrs/ (http://www.bearchive.com/~tndvrs/)

(http://forum.bearchive.com/index.php?action=profile;u=585)

Lesbian Bob (http://forum.bearchive.com/index.php?action=profile;u=585)

F Cup

875

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41561#msg41561)
« **Reply #56 on:** September 10, 2002, 09:37:32 PM »

A problem with comparing different time periods is that technology changes with time, but if you compare different countries over the same periods you should be able to see which are more advanced than others.

Why don't the countries with the least amount of medical technology regulation have the most advanced medical technology? My guess is that government regulation isn't as much a hinderance as some think.

Logged

(http://forum.bearchive.com/index.php?action=profile;u=1833)

ninjrk (http://forum.bearchive.com/index.php?action=profile;u=1833)

F Cup

685

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41564#msg41564)
« **Reply #57 on:** September 10, 2002, 10:35:22 PM »

Well, we could look south of the border for a good example. There is little effective regulation of drugs in Mexico and it is estimated that thousands die because of that every year. It's further estimated that tens of thousands suffer moderate to long term health problems because of the same drugs, due to poor quality control or outright fabrication. Indonesia and India are two other good examples.

It's also worth noting that the enhanced regulatory responsibility didn't happen because someone woke up and thought "gee, we should have Congress expand the powers of the FDA". The imediate impetus was the Thalidomide disaster, where 1000's of babies were born with substantial birth defects of the limbs. Ironically, at the time the FDA saw no reason for the drug to not pass. Fortunately, it went to their newest reviewer, Dr. Frances Kelsey. She got shit for 2 years for demanding to see conclusive proof both from the media and industry. Then, reports started trickling in about problems. Of the 10,000+ babies born with defects, less than 2 dozen were American because she stood up to them. The public was quite happy, until they realized that the FDA would have normally passed it except for one person, who was also hammered by her FDA bosses. Needless to say, the collective public response was anger that it could have happened and they demanded reform, which they got. Amusingly

have happened and they demanded reform, which they got. Amazingly, the safety stuff had been in place since 1938, the FDA was just shamed into enforcing it better. One of the two main changes came about because of the variability in manufacturing and the lack of effectiveness of drugs. Contrary to the crap that you'll find on-line, little of the 1962 Kefauver-Harris drug amendments concerned safety regulation (which is ironic, considering that it was safety that drove it) but rather mandated that the FDA start assessing drugs for efficacy. Plenty of drugs were cleared prior by the FDA that wouldn't kill you, they just wouldn't help you either. Most important was the GMP regs that came out, which required manufacturing to provide consistent content and quality of drugs, rather than the previous requirements that only concerned sanitization. It also mandated that drug labels actually list the compound name and any side effects. Sorry to say, most of the changes were the regulations in manufacturing, labeling, and efficacy, NOT safety. Most of the safety regs date back to 1938. Something all those anti-FDA websites don't realize. I doubt if 1 in 10 authors has actually read the amendments.

When it comes to implants, the FDA didn't get authority until 1976 with the medical device amendments.

To be blunt, I've seen lots of books, articles, and websites talking about the thousands dying of no new drugs. They never seem to mention which drugs those would be. Death rates have plumetted in the last 30 years. Life expectancy is higher than ever. People with cancer, heart disease, organ failure, etc live far longer than they did 30 years ago. Yet somehow, we're supposed to believe that we're worse off or that some miracle medication is laying with the water-powered cars and oil substitutes. Why do we think these drugs are miracle drugs? Because early phase 1 and 2 studies show it's promise. To be blunt, those drugs aren't abandoned. They are snapped up and pushed through. It's interesting how many of those wonder drugs hit the papers and then quietly disappear. Not because they are repressed, but because they don't pan out.

As for news shows, do you remember peach pits curing cancer? All those experimental cancer and HIV cures down in Mexico? The news shows do those all the time, usually showing some FDA suit droning on about safety while the gleeful couple talk about how they feel so much better now. Every so often, they do a follow-up where they mention that they croaked. They almost never discuss the hundreds more who died trying it.

I would argue that the FDA needs to increase staffing, streamline drug passage (the departmental redundancies are horrid), and embrace new technologies. Finally setting standards for electronic data capture beyond CFR part 11 would be lovely. To argue that we would be better off without any regulations is silly. BTW, the notion that Europe is different is also silly. I've worked in the labs there on a 14 month exchange. Much of the safety stuff is done and looked at during study conduct rather than waiting for a final complete package. So, they have much of the work done during, which lengthens the development time. The same studies are done, just assessed at different times. Here's a shock for you. If you wait to send a complete package like most US companies do, same studies, same data, same safety and efficacy assessments, it is often EASIER to get a drug approved in the US than Europe. Don't even get me started on getting it into Japan. I've been on teams that have sent packages to all of the main regulatory agencies. Europe is also notorious for approving some drugs more quickly (it's rare, it's usually politically

motivated, but it happens) and just when you have the millions of bottles ready, they suddenly make it provisional again, and they want the tests run in country. How convenient. Where Europe is looser is in medical devices, whcih takes us back into implants. Note all of the horror stories of cosmetic surgery in Mexico and SE Asia. It's cheap, it's easy, and sometimes you actually come home without rampant infections! What a deal!

Look, this is so far off-topic that it's not funny. I've said my peace, the field is yours. This is way to much work for the satisfaction. I'm just going to look at boobs now!

Matt

Logged

Logged

Be nice to everyone you meet, but have a plan to kill them if you have to.

"the only thing unnatural about my tits is how fucking amazing they are!" LOL

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41589#msg41589)
« **Reply #58 on:** September 11, 2002, 02:11:55 AM »

(http://forum.bearchive.com/index.php?action=profile;u=769)

Connoisseur (http://forum.bearchive.com/index.php?action=profile;u=769)

E Cup

343

> In reply to:
>
> A problem with comparing different time periods is that technology changes with time, but if you compare different countries over the same periods you should be able to see which are more advanced than others.

You want to compare situations in which everything other than the factor of interest has changed as little as possible. That criterion is better satisfied by comparing the U.S. in 1961 to the U.S. in 1963 that it is by comparing, say, France in 2002 to the U.S. in 2002.

> In reply to:
>
> Why don't the countries with the least amount of medical technology regulation have the most advanced medical technology?

All other factors being equal, I believe it <I>is</I> the case that countries with the least regulation have the most medical innovation. The problem with international comparisons is that all other factors are not equal. For example, if we eliminated all medical technology regulation in Cameroon, we wouldn't expect innovation to suddenly flourish there, because there are so many other factors, such as endemic poverty and low literacy, working against that.

Moreover, I wouldn't want to live in a society with literally zero medical regulation anyway, even though I believe that medical innovation might be faster there. In such a society there would be a privileged class of people – doctors – who would be permitted to abduct any non-doctor from the streets and perform with impunity medical experiments on them. While I'll confess that the idea applied to breast augmentation research is alluring, this still isn't the sort of society in which I'd want to live, even if it had succeeded in curing cancer and heart disease.

Logged

Re: the FDA (http://forum.bearchive.com/index.php?topic=40100.msg41606#msg41606)
« **Reply #59 on:** September 11, 2002, 06:02:23 AM »

(http://forum.bearchive.com/index.php?action=profile;u=769)

Connoisseur (http://forum.bearchive.com/index.php?action=profile;u=769)

E Cup

343

We agree on one thing. It' time to get back to talking about huge tits. But before we do, a few closing points are in order.

1) You seem to think that eliminating the FDA (or merely its power to ban) is tantamount to eliminating all regulation.

Wrong. Look, we live in a society in which you can http://www.news.com.au/common/story_page/0,4057,4785408%255E13762,00 (<a href=)">sue McDonald's for making you fat, and you won't get laughed out of court. A functioning system of torts deters corporations from flooding the market with killer drugs. That system is stronger now than at any time in U.S. history. No company large or small makes a move today without first consulting a lawyer. The problem with the FDA is that it stands outside of this system. No matter how much harm it does, because it's government agency, it can't be sued.

In Mexico, The People's Republic of China, standard dictatorships and other countries ruled by a corrupt clique or party, the tort system generally doesn't work. It would be extremely difficult for a Mexican peasant to successfully sue a corporation, because the corporation would win by bribing judges and other government officials. Remember, the same party ruled Mexico for 71 years. Coincidence or corruption? You decide.

2) You discount the fact that the FDA is staffed by human beings motivated by the usual degree of self interest.

You shouldn't. The FDA is staffed by people with mortgages, car loans, and [censored] in college. Given that their interest in job security at least on occasion conflicts with the public interest, we should be astounded if they always acted to promote the latter. They're not saints, after all. This means that they are not regulating in such a way as to maximize public benefit, which means that people are suffering and dying unnecessarily.

Moreover, a system that allows a few bureaucrats to make decisions that could literally cost corporations billions of dollars is a recipe for corruption.

Lastly, like any government agency, the FDA is inefficient. Testing takes longer and costs more than it should because, unlike a private company,

the FDA's existence isn't jeopardized by its inefficiency. Again, that means that people are dying who need not.

3) You don't seem to be getting the point that *the minimization of death and suffering caused by FDA approved drugs is not the same as the minimization of total death and suffering*.

Let's say that the FDA had approved thalidomide. Let's say that thalidomide did worse than deform 10,000 babies, let's say it killed them. FDA could compensate for that by, for example, approving the Ambu Cardio pump, which is available in other industrialized countries and would save 7000 lives per year in the U.S. Or it could have speeded up its approval of certain beta blockers (which had been in use in Europe), interleukin-2 (also in European use) or streptokinase easily saving tens of thousands of lives.

4) Lastly, you don't seem to acknowledge that the FDA effectively assumes that all patients are equally risk averse.

You should. Consider this exchange between you, terminally in the hospital, and your doctor.

You: How long have I got, Doc.
Doctor: About two days.
You: Isn't there anything you can do?
Doctor: Well, there's a treatment which has had excellent results on

patients just like you in Europe, but the FDA hasn't approved it for use here. It's took risky.
You: I'll take the risk!!
Doctor: That's not your decision to make. It belongs to the head of the FDA.
You: I'll waive my rights to sue! I'll sign anything! I'll pay anything! Anything!!
Doctor: I'm sorry, there's nothing I can do.

==========

Okay. I'm done. I'm really, really sorry going this far OT. Not another word from me except about huge tits.

Logged

Print (http://forum.bearchive.com/index.php?action=printpage;topic=40100.0)

Pages: 1 (http://forum.bearchive.com/index.php?topic=40100.0) 2 (http://forum.bearchive.com/index.php?topic=40100.15) 3 (http://forum.bearchive.com/index.php?topic=40100.30) [**4**]

Threads: « previous (http://forum.bearchive.com/index.php?topic=40100.0;prev_next=prev#new) | next » (http://forum.bearchive.com/index.php?topic=40100.0;prev_next=next#new)

Jump to: => Real World Breast Enlargement Options / Information go