Title VII of the Patient Protection and Affordable Care Act

MAJ McGee, MAJ Skinner, Capt McLain

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What is Title VII????

IMPROVING ACCESS TO
INNOVATIVE MEDICAL THERAPIES

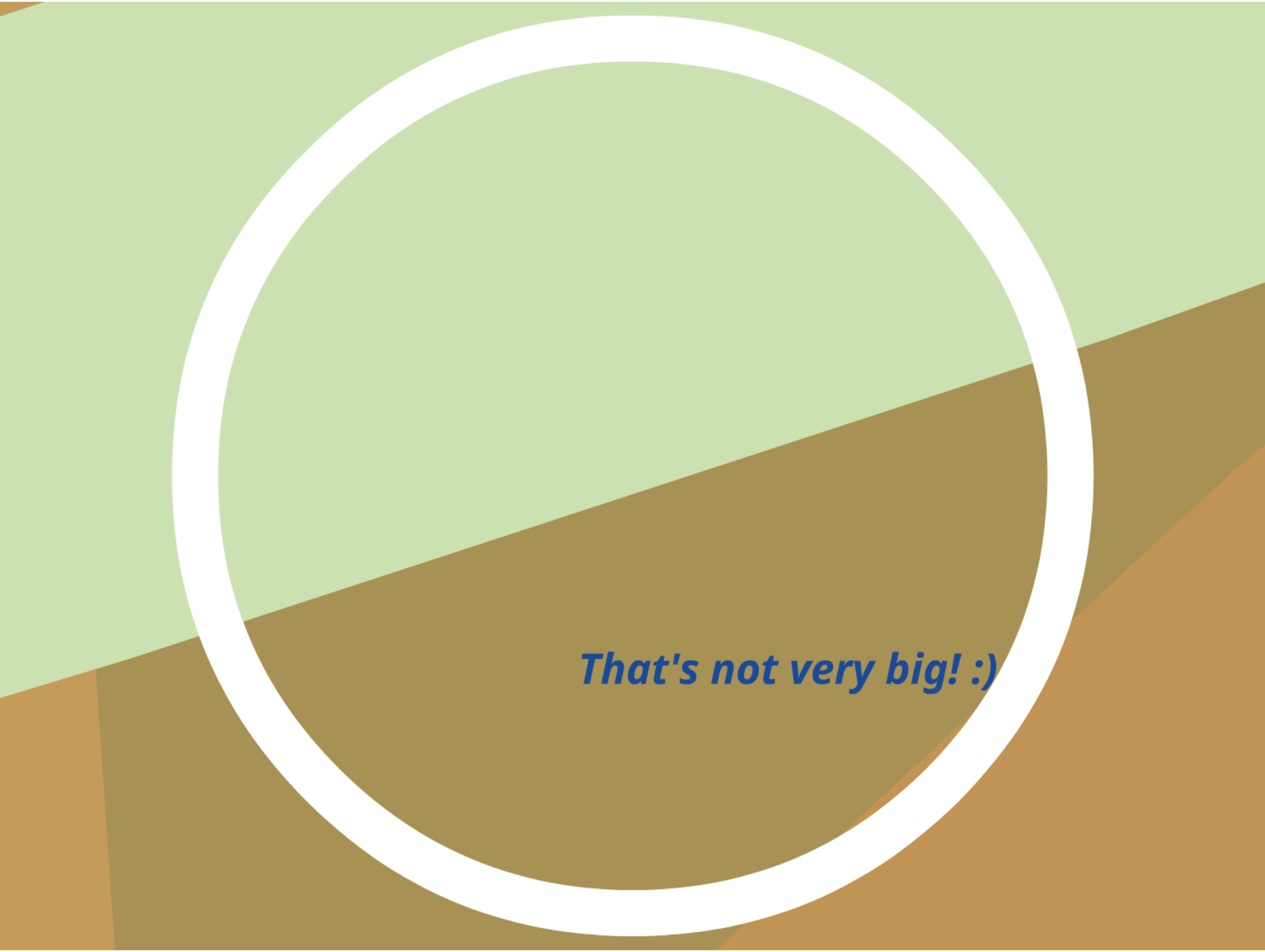
How Big Is It?????

A paltry 10,938 words.

The Entire ACA is 418, 779 words!

So?

So, Title VII is only 2.6% of the total.


That's not very big! :)

What does it do????

What does it do, you ask?

"It is the sense of the Senate, that a biosimilars pathway balancing innovation and consumer interests should be established"

What does that mean?

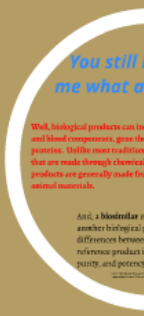
Well, it's supposed to help make biosimilar drugs more readily available, while also protecting pharmaceutical companies from patent infringement.

Title VII also improves access to innovative medical therapies and extends discounts on drugs.

Huh?

The goal of the 1st part is to offer more medicinal ways of treating illnesses beyond the chemical medications that have already been approved and prescribed for use by using biosimilar biologic medicines.

The goal of the 2nd part of Title VII addresses more affordable medicines for children and under served communities.



http://www.mcnlearning.com/news/affordable-care-act-titles-vii-and-viii/Affordable Care Act: Titles VII and VIII

You still haven't told me what a biosimilar is!

Well, biological products can include vaccines, blood and blood components, gene therapy, tissues, and proteins. Unlike most traditional, prescription drugs that are made through chemical processes, biological products are generally made from human and/or animal materials.

And, a **biosimilar** is a biological product that is similar to another biological product and there are no meaningful differences between the biological product and the reference product in terms of safety, purity, and potency.

http://www.fda.gov/Drugs/DevelopmentApproval?rocess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm

Saaaweeeeeet!

That is awesome! Biologics are widely used here and biosimilars are very common in the rest of the world. They are viewed as effective. Also, because they are biologic, there can be many versions because....well.....biology :)

https://www.bio.org/articles/how-do-drugs-and-biologics-differ

Soooo....

I'm going to run out and grab me some biosimilars. Yeah, free market!!!

Where are they?

To date, FDA has not approved a biological product as biosimilar or interchangeable. Since passage of the Affordable Care Act in 2010, the FDA has been establishing standards for licensure to ensure the safety and effectiveness of biosimilars.

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm

How can that be?

No approval of an application as either biosimilar or interchangeable is allowed until **12 years** from the date on which the reference product is first approved.

http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf

12

YEARS?!

GTFO!

.AAAAND, if FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS cannot make a determination that a second or subsequent biological product is interchangeable to that same reference product until **1 year** after the first commercial marketing of the first interchangeable product.

http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf

Awesome...

So, I guess we'll see some real headway soon...

This is how we define progress.

Is there anything encouraging about this part of Title VII?

ummm....if you have a prescription for the reference product, you don't need a new script for a biosimilar.

Companies have to alert competitors when they're starting a marketing campaign for a biosimilar.

The government can't charge more than actual costs it incurs to review an application for licensing a biosimilar.

There is some more. It's not all bad.

Part 2

More Affordable Medicines for Children and Underserved Communities

EXPANSION OF COVERED ENTITIES RECEIVING DISCOUNTED PRICES

1) does not receive Medicaid money

2) is a critical access hospital

3) is a hospital in a rural area

HOW?

By expanding the 340B drug pricing program.

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. http://www.hrsa.gov/opa/index.html

Reduces cost by 25-50% of Average Wholesale Price

https://docs.340bpvp.com/documents/public/resourcecenter/faq/FAQs_340B_Price_Drugs_340B_Price.pdf

So who sets ceilings, and how?

The drug companies help set the ceilings?

Really?

This price is set based on the Average Manufacturer Price (AMP), minus a discount (usually equivalent to the state Medicaid Drug Discount Program rebate).

https://docs.340bpvp.com/documents/public/resourcecenter/faq/FAQs_340B_Price_Drugs_340B_Price.pdf

http://americanactionforum.org/research/primer-understanding-the-340b-drug-pricing-program

Whew.....

That could have gotten ugly.

Are there penalties if a drug company overcharges under the program?

But there IS oversight.....

The ACA tasks HHS to verify the accuracy of ceiling prices calculated by manufacturers.

AND....

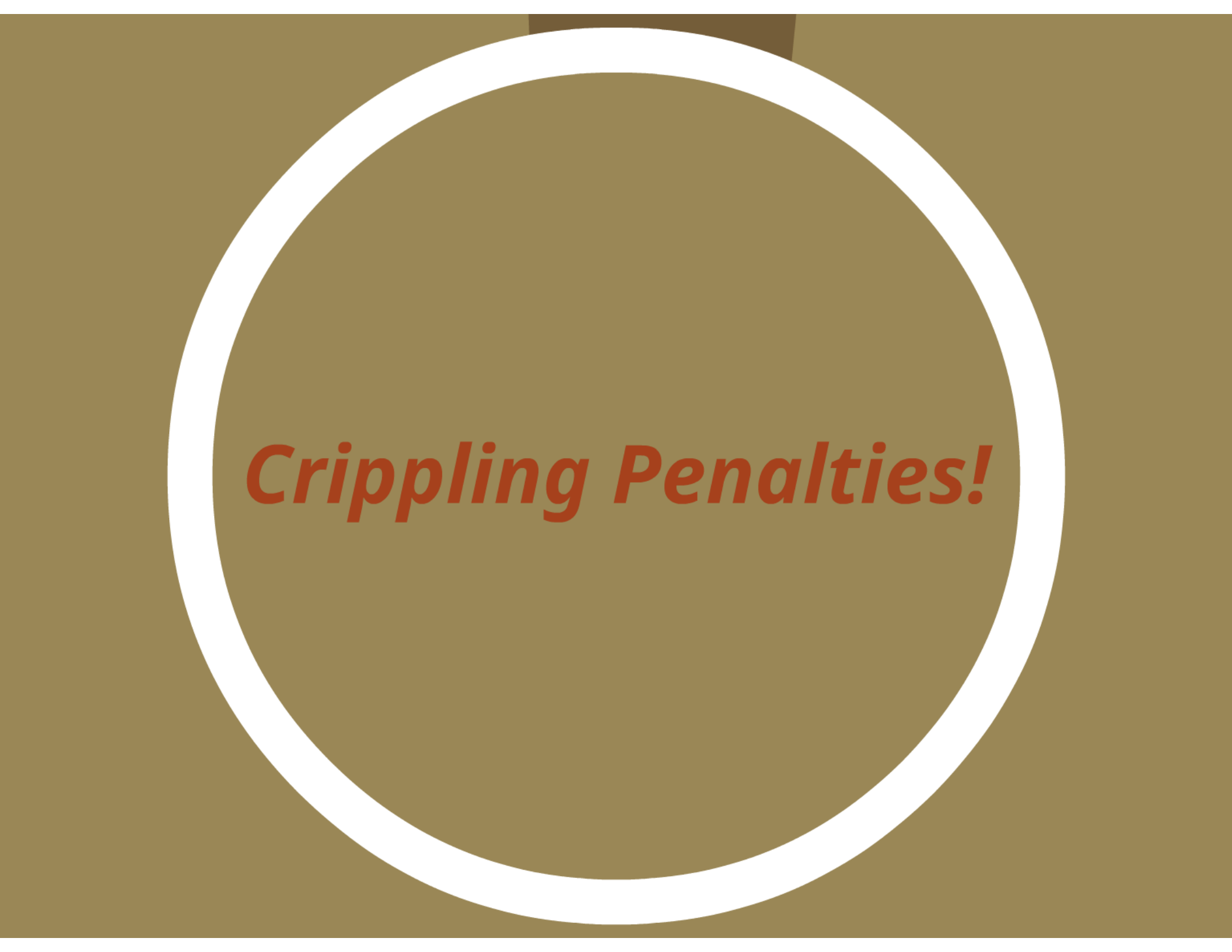
HHS performs spot checks of sales transactions by covered entities.

Whew.....

That could have gotten ugly.

Are there penalties if a drug company overcharges under the program?


YEP!!!


Crippling Penalties!

...shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred.

Found for Sale: 1987 Yugo GV Sport with only 1,800 miles

Wednesday, July 21, 2010 at 7:42 pm | Posted by **Carscoop Carscoop**

FILED UNDER CLASSICS | FIAT | OFFBEAT NEWS

34 Comments +1 +1 Recommend this Like Share

This hardly ever used 1987 Yugo GV Sport (don't take the "Sport" part of the name seriously), which has seen a mere 1,800 miles on the road, is up for sale by a Las Vegas car dealer. The asking price is $14,500, which is a long wa off from the car's original sticker in the late 1980s.

So, ultimately, who benefits?

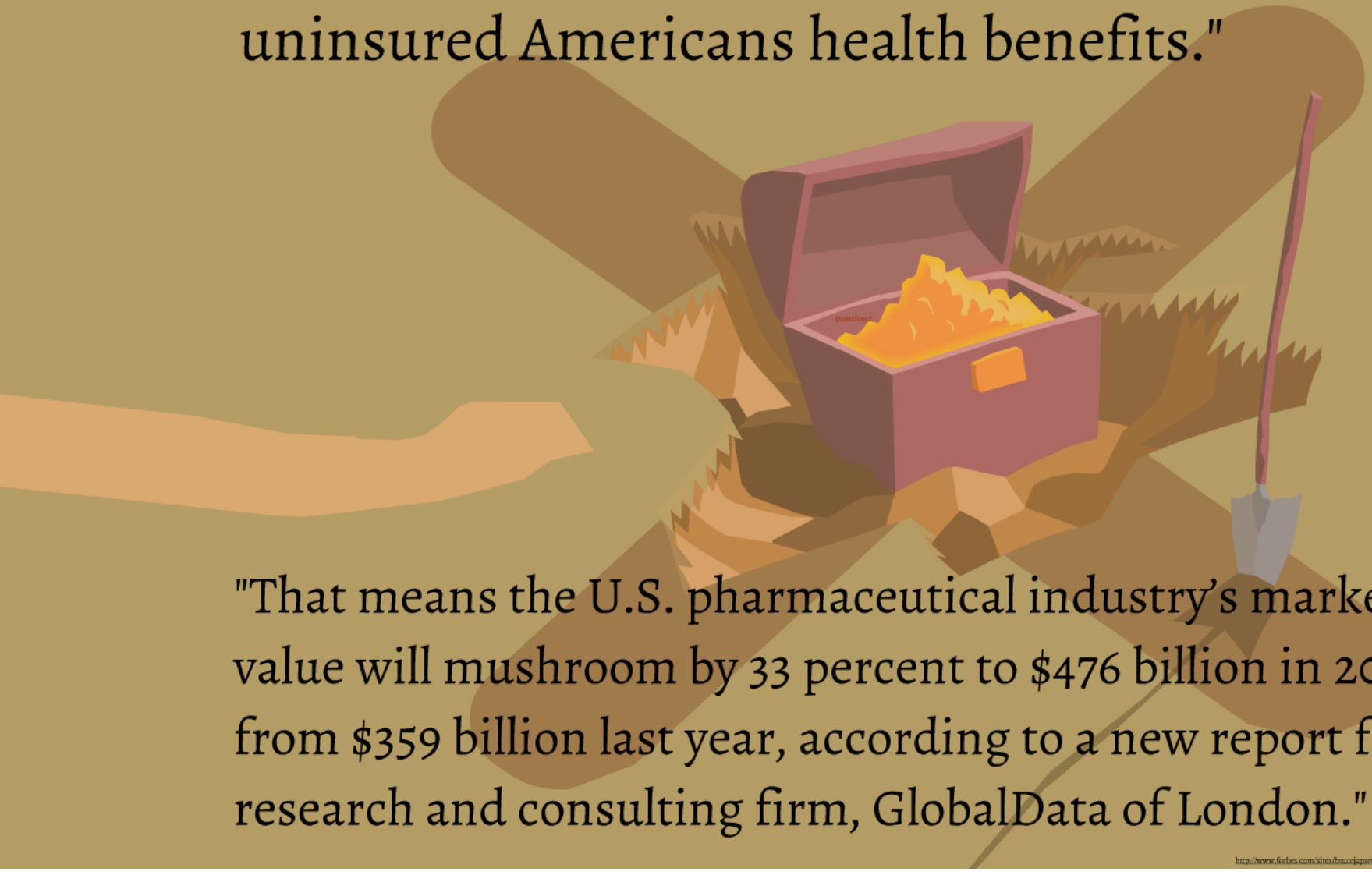
We benefit. There will (should) be increased competition and innovation, eventually.

More people will have access to meds in poor areas.

and.....

Obamacare Will Bring the Drug Industry Billions

"The health law, which will bring millions of uninsured Americans health benefits."



"That means the U.S. pharmaceutical industry's market value will mushroom by 33 percent to $476 billion in 2020 from $359 billion last year, according to a new report from research and consulting firm, GlobalData of London."

http://www.forbes.com/sites/brucejapsen/2013/05/23/obamacare-will-bring-drug-industry-35-billion-in-profits/


Questions?


Thank you!

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