Ethics in Pharmacy Practice: What is Truth?

Virgil Van Dusen, R.Ph., J.D. SWOSU College of Pharmacy Weatherford, Oklahoma

What is truth?

- Basically it is the honest conveyance of facts or reality.
- The opposite of truth is a lie.
 - A lie is a statement or statements that one knows to be false or a deception.

Truth

- Truth has been a topic of discussion in its own right for thousands of years.
- Even Pontius Pilate asked the question: "What is truth?" Matt: 12:36

Our Society Needs Truth and Expects It!

- Oath: I swear that the evidence that I shall give, shall be the truth, the whole truth and nothing but the truth, so help me God.
- The pharmacy profession has expected the truth for decades by providing Codes of Ethics.
 - 1852 APhA Code of Ethics: ...when repetitions of frauds occur, they should be exposed for the benefit of the profession.
 - 1994 APhA Code of Ethics: A pharmacy has a duty to tell the truth and act with conviction of conscience.

The Pharmacy Profession is Recognized as Being Highly Ethical



All in Society Should Be Held to a Standard...

To Tell The Truth!

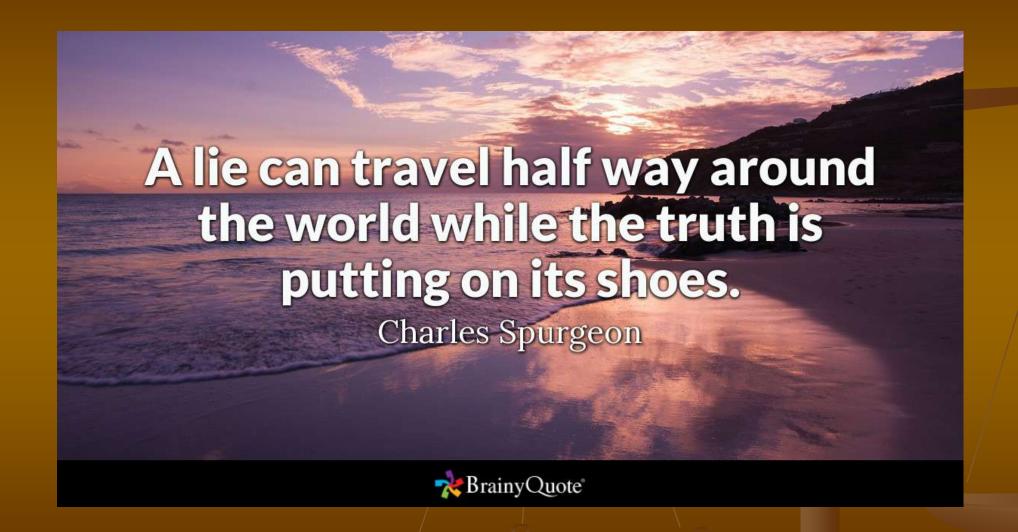
Yet lying is common and profitable...even in our world of pharmacy.

There Are Different Types of Lies

Lies of Commission

This type of lie is telling someone something that is simply not true.

• An example would be telling someone that a drug is perfectly safe when it has a black box warning.



There Are Different Types of Lies

- Lies of Omission
- This type of lie is one where you leave out an important part of information.
- This type of lie is harder to spot.
- This type of lie is when you know there are potential serious side effects of a drug a you choose not to share them.

There Are Different Types of Lies

- Then there is the lie of influence.
- These kinds of lies make you believe the liar.
- A person asks if St. John's Wort is good for depression and you share that you've been selling it for 20 years.

What Are the Results When One is Caught in a Lie?

■Trust is lost. Maybe forever.

Would the World of Pharmacy Ever Advertise a Product to Treat the Common Cold?

- In the 1970s the FTC ordered Warner-Lambert to cease and desist misrepresenting the efficacy of Listerine mouthwash against the common cold.
- W-L claimed there was no evidence to prove to the contrary.
- Yet the facts, the truth, showed their lies.
 - Warner-Lambert Co. v. Federal Trade Commission, 562 F.2d 749(D.C. Cir. 1977)

The FTC Showed the Following to be True:

- The ingredients of Listerine are not present in sufficient quantities to have any therapeutic effect.
- It is impossible for Listerine to reach critical areas of the body in significant concentration through gargling.
- Even in they could reach critical sites, they could not penetrate cells and, thus, could not affect viruses.
- W-L's studies were unreliable.
- Even in Listerine kills millions of germs, those germs played no role in colds.

Surely No One Would Advertise Again a Product to Treat the Cold...or Would They?

- In 2010 Walgreens agreed to pay \$6 million dollars to the FTC for having misleadingly publicized (LIED) that their Wal-Born supplement line could successfully fight germs, prevent colds, and increase the immune system.
- However, Wal-Born products failed to treat the symptoms of cold or flu.
- The company did not have any scientific proof or confirmation for any of its claim.
- http://settlementonline.blogspot.com/2012/11/claim-walgreens-wal-born-settlement-on.html

The purpose of many federal acts are to assure truth.

- Pure Food and Drug Act of 1906
 - Addressed ingredient labeling of drugs
- Food, Drug and Cosmetic Act of 1938
 - Required information about the safety of medications
- Nutrition Labeling and Education Act of 1990
 - Mandates nutrition labeling on food products and authorizes some health claims
- OBRA-90
 - To assure patients knew not only how to take their medication but also knew the risks as well.

But there is one Act that allows lies:

- Dietary Supplement Health and Education Act of 1994
- This Act passed based on intense lobbying.
- The dietary supplement manufacturers felt that the a previous act (NLEA) left too much authority with the FDA and unduly restricted the promotion of dietary supplements.
- This now allows certain claims that otherwise would have been illegal until the FDCA.
- In essence, the FDA regulates dietary supplements more as foods than as drugs.

What Claims the DSHEA Allows:

- 1) Statements that the product will benefit a classical nutrient deficiency disease.
- 2) Statements that describe the role of the product in affecting the structure or function of the body.
- 3) Statements that characterize the documented mechanism by which a DS acts to maintain the structure or function
- 4) Statements describing the general well-being from the use of the DS (e.g. energizer, relaxant, muscle enhancer)

FACTS

- Three in four Americans now take at least one dietary supplement on a regular basis.
- The dietary supplement industry has expanded to include as many as 80,000 different products for consumers.
- On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products that make false claims as to therapeutic effectiveness.
 - Oklahoma Board of Pharmacy Newletter (April, 2019)

From That the World of Crazy Claims!

- Cila Minerals made dietary supplements that could treat or cure almost anything!
- Such as: ALS, brain injury, diabetes, cirrhosis, autism, epilepsy, cataracts, hepatitis, stroke, depression, high cholesterol, high blood pressure, yeast and viral infections, AIDS, heart disease, glaucoma, shingles, whooping cough, herpes, and on and on.
- https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm446541.htm?source=govdelivery&utm_mediu m=email&utm_source=govdelivery

The Labels May Not Tell the Truth as to the Ingredients.

- The New York Attorney General accused four major retails of selling herbal products that contained little to no active ingredients.
- The retailers were GNC, Target, Walgreens and Walmart.
- The products were found to contain rice, beans, peas, and wild carrots.
- Some contained legumes, such as what grows peanuts and soybeans, to which many are allergic.
- https://well.blogs.nytimes.com/2015/02/03/new-york-attorney-general-targets-supplementsat-major-retailers/

In Some Cases These Products are Recalled

- Because they are representing themselves as drugs in that they can cure Alzheimer's
 - https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631064.htm
- Or because they contain actual drugs such as:
 - Fluoxitine
 - Sildenafil
 - Anabolic Steroids
 - https://www.consumerreports.org/dietary-supplements/dietary-supplementsfound-tainted-with-prescription-meds/

What About Truth Issues and Prescription Drugs?

- Usually people don't ask us too much about prescription drugs.
- But we have the opportunity at times to counsel them.
- Hear is a comfortable counseling session:
 - "This drug may cause nausea, diarrhea, or headache."
- We like to counsel over what is non-threatening.
- But what if the drug has a black box warning?

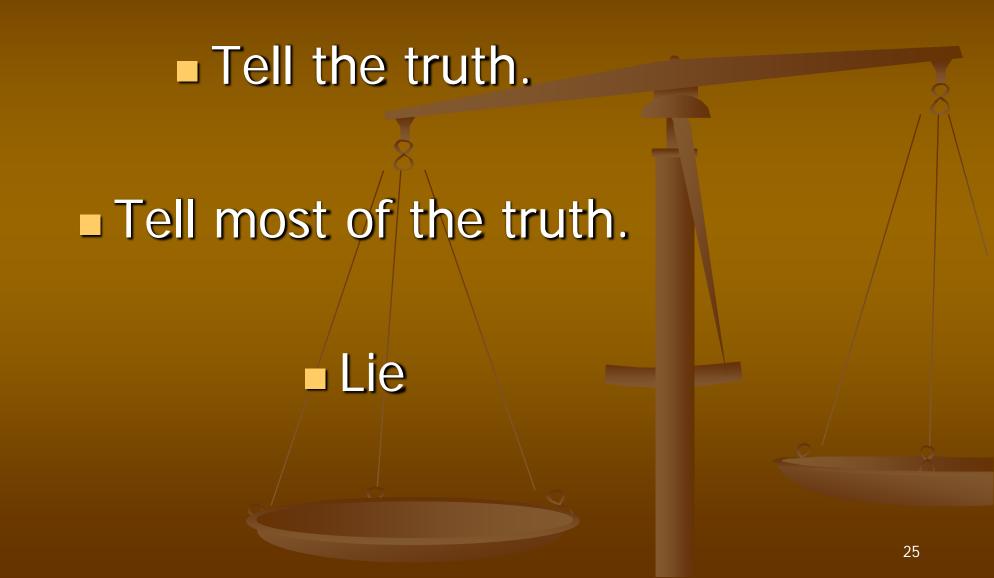
Let's Talk About A Drug You Know Well



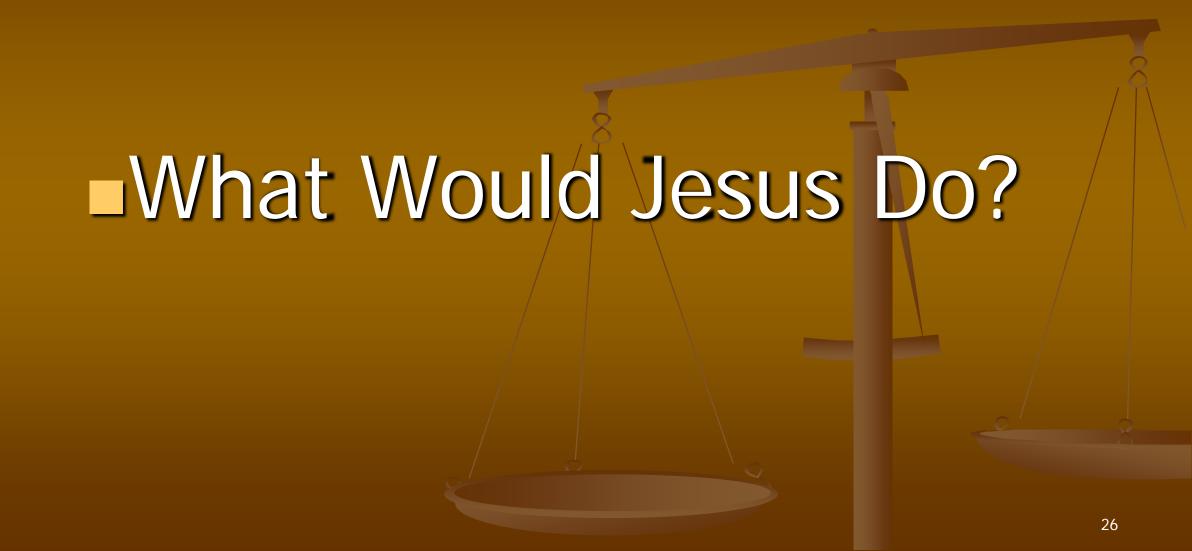
So Where Do We Go From Here?



We Need To Look At Our Options



Maybe We Should Ask...



What Does the Word Say?

- Jesus said the Devil was the father of lies. John 8: 44
- Jesus said there is no truth in him.
- But it seems easy to believe his lies.
- As a matter of fact, the first time that man had to make a choice between God's truth and the devil's lie, he chose the devil's lie.
- Our sinful nature often sides with the devil's lies.

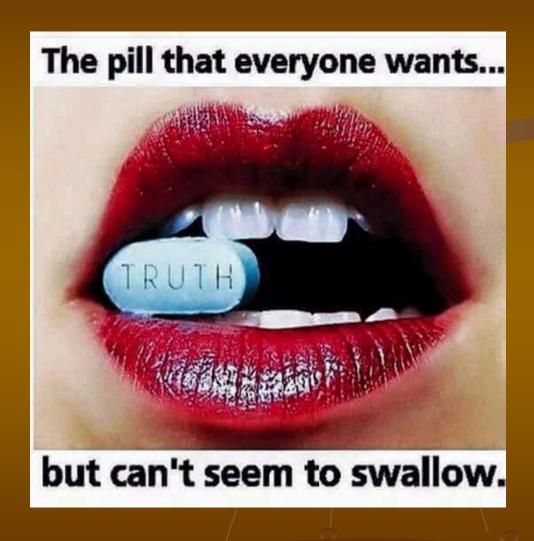
As Believers We Are Held to a High Standard

- But that doesn't mean that telling the truth will be easy.
- We will be tempted to dilute it, abandon it, or cover it up.
- There will be those who ask us to lie.
- Some may even encourage us to go along with a lie.
- And greed may be the sin that propels us to lie.
 - Maybe that's what happened to this pharmacist.

Let's Face It—Sometimes the Truth Hurts

- The truth is man has a sin nature.
- "Out of the heart proceed evil thoughts..." Matt. 15: 19

- The truth is that someday there will be judgment.
- "Every idle word men may speak, they will give an account of it in the day of judgment." Matt. 12: 36



The Greatest Truth is that Jesus Is Truth.

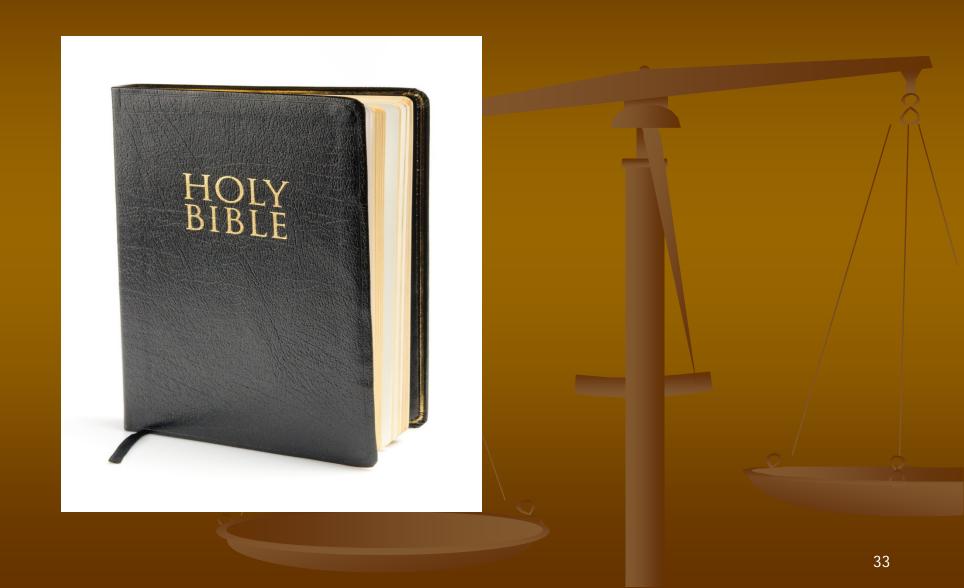
- He is the truth about who God is.
 - He tells the truth about man.
- He tells the truth about the devil.

Each One of Us Has a Moral Compass





That Moral Compass Is Based On This



As With Any Ethical Decision...



We have a choice to listen to the...



I am the Way, the Truth, and the Life. No one comes to the Father except through me. Jesus Christ *BrainyQuote

Questions?