SPANGENBERG LAW FIRM

April 2015

POINTS OF INTEREST

NEWS AND VIEWS OF THE SPANGENBERG LAW FIRM.

IN THIS ISSUE:

NEW PREGNANCY LABELS ON PRESCRIPTION DRUGS

BY: PETER J. BRODHEAD, ESQ.

Beginning on June 30, 2015, the FDA will have a new and long overdue rule on labeling for certain drugs, including Zofran (the brand name for the drug Ondansetron), as to certain categories including pregnancy. All new drugs must comply immediately, and the compliance date for existing drugs will be phased in over time.

Under the new rule, the pregnancy section of the new labels must now provide information pertinent to the use of the drug in pregnant women, such as dosing and potential risks to the developing fetus, and will require information about whether there is a registry that collects and maintains data on how pregnant women are affected when they use the drug. This could include information on disease-associated maternal and/or embryo/fetal risk, dose adjustments during pregnancy, and maternal adverse reactions as well as fetal/neonatal adverse reactions.

The FDA believes that including such information supports health care providers' understanding of drug product risks and benefits and facilitates informed prescribing decisions and patient counseling. The drug label must also describe the data that serve as the basis for the risk statements and clinical information included in the "pregnancy" section of the labeling.

For quite some time now, the FDA has recommended to drug companies, including GlaxoSmithKline (GSK) - which made Zofran - that they include in their labels the existence of any pregnancy registries and provide helpful information about them. GSK, however, has never voluntarily included such information in their labels. This is disturbing, given the number of Adverse Event Reports of congenial anomalies filed in connection with the use of Ondanestron. Under the new rule, GSK must do so.

It is astounding that GSK has not changed its pregnancy labeling language for Zofran in any meaningful way throughout the 24 years that its product has been on the market. At least one settled civil suit alleged that GSK through its representatives in the field had encouraged the off-label use of Zofran to treat morning sickness in pregnancy, even though the FDA has never

(Continued on next page.)

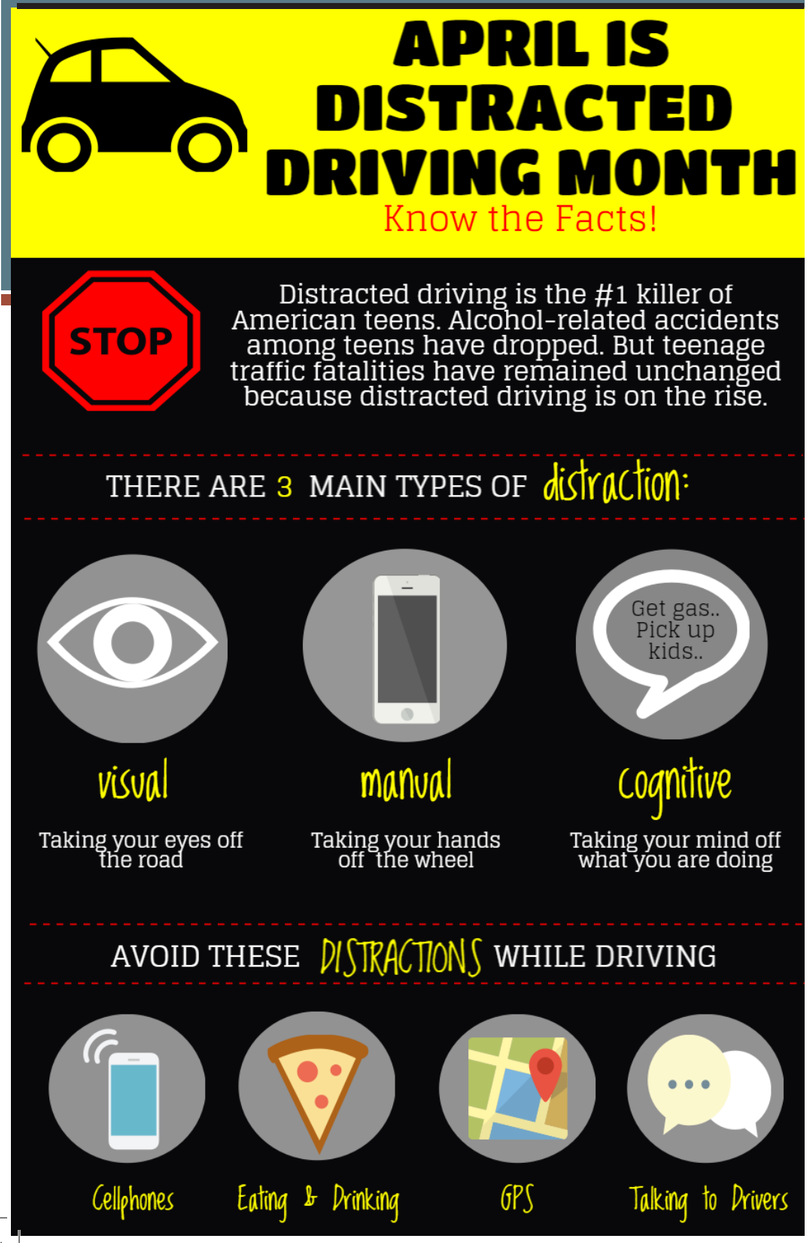
NEW PREGNANCY LABELS (continued)

approved it for this purpose.

Many scientists and physicians who have studied Zofran (ondansetron) and birth defects have come to the conclusion that taking Zofran during early pregnancy significantly increases the risk of cleft lip, cleft palate, and cardiac defects.

By contrast, the labels on prescriptions for Ondansetron in many foreign countries have long contained warnings for pregnant women, such as "Caution When Used During Pregnancy" and "Do not take ONDANESTRON if you are pregnant, or likely to get pregnant."

Zofran eventually became the Number One prescription drug in this country for the treatment of nausea and vomiting in pregnancy? How did this happen? ◆



SAFE TEEN DRIVING: GET RID OF DISTRACTIONS

BY: WILLIAM B. EADIE, ESQ.

As we enter April, national Distracted Driving Awareness Month, consider some alarming but sadly predictable research from the AAA Foundation for Traffic Safety: distracting teen drivers leads to crashes. As the study authors concluded, a teen driver involved in studied crashes "was inattentive or engaged in some other non-driving-related activity in 58% of crashes overall (44% of loss-of-control crashes, 89% of road-departure crashes, 76% of rear-end crashes, and 51% of angle crashes)." Distracted by what? Mostly passengers and cell phone use.

How do you help ensure teens don't drive distracted? One way is to set limits on teens driving together, without adults. The study found that of passenger-present crashes, "84% of passengers were estimated to be ages 16-19; fewer than 5% were parents or other adults."

Another way is education. I've been presenting on distracted driving at area schools using a program from the program at *EndDistractedDriving.org*. Check out the website for information. You can even download and present the program yourself, a worthy, potentially life-saving project. And feel free to contact me with questions, or if you have a group to whom you would like me to make a presentation on this topic. This presentation is a tested, effective method to change teen behavior; I'm just happy to be one of many messengers helping spread the word.

Check out and share the full 2015 Teen Crash Causation Report at **www.spanglaw.com/teencrashreport** ◆

HERBAL SUPPLEMENT FRAUD UPDATE

BY: DANIEL FRECH, ESQ.

The dietary supplement industry – the folks selling everything from ginseng to fish oil to colloidal silver to bee pollen – is big business. Over $13 billion dollars of business on an annual basis. While the industry likes to imagine itself part of the "health-care" economy, there has long been debate in the popular and scientific press about whether the best-known supplements in this industry - Ginkgo biloba, Valerian root, St. John's wort - actually provide the benefits their advocates claim.

As it turns out, however, the effectivenss of its products may prove to be the least of the supplement industry's problems, at least in the short term. Why? Because testing by the New York Attorney General has found that the dietary supplements at several major retailers – at least their private label "store brands" – are an out-and-out fraud. As in: the product identified on the label is not contained in the pills in the jar. As Tim Egan wrote in the New York Times in February, "The labels say Ginkgo biloba, or ginseng, or St. John's wort. But testing announced by the state of New York this week found that the Ginkgo biloba sold by Walmart, for example, contained no Ginkgo biloba DNA — it was a mixture of rice, mustard, wheat and radish." Similar results were obtained for most other supplements.

The New York Attorney General ordered the retailers – Wal-Mart, Target, Walgreens, or GNC – to remove the items from their shelves. Further regulatory investigations and a spat of class action lawsuits quickly followed. The incident raises troubling questions about the generally unregulated dietary supplement industry and who, if anyone, will be held accountable for the large scale defrauding of consumers.

We at The Spangenberg Law Firm are troubled by the facts uncovered by the New York Attorney General. If you have purchased private label or "store brand" Ginkgo Biloba, Ginseng, or St. John's Wort at Wal-Mart, Target, Walgreens, or GNC over the past two years and are interested in discussing the matter with an attorney, please contact our office at (877) 696-3303. ◆

MANDATORY ARBITRATION: A BAD DEAL FOR CONSUMERS

BY: DANIEL FRECH, ESQ.

You may have experienced this first hand: you make a major consumer purchase and the paperwork that you have to sign has a "mandatory arbitration" clause, or it requires that you waive your right to participate in a future class action lawsuit.

The Federal Consumer Financial Protection Bureau ("CFPB") just released a study last month that confirmed a simple fact that attorneys who represent individuals in class action lawsuits have known for years: those mandatory arbitration clauses and class action waivers provide no benefit to consumers and instead, serve only to protect the banks and other companies that frequently use them.

In the most thorough research study ever done on the issue, the CFPB examined how consumers sought (and obtained) relief for what they viewed as unlawful or unfair consumer practices by consumer finance companies - such as banks, mortgage servicers, and credit card companies.

- Only 600 consumers per year sought relief from financial services providers through arbitration and only 1,200 sought relief by filing a case in federal court.
- Those arbitrations resulted in less than $400,000 total being returned to customers. The federal court cases were similarly unsuccessful or resulted in small recoveries.
- On the other hand, roughly 32 million consumers per year obtained relief from financial services providers through class action litigation.
- These class action cases – even once attorney's fees and litigation expenses are accounted for – returned over $220 million dollars to American consumers.

Looking at the numbers, it is obvious why banks like mandatory arbitration and dislike class actions lawsuit. When it comes to obtaining legal relief for consumers, class action lawsuits work. Arbitration serves only to benefit the banks and deny Plaintiffs their right to go to court.

The hope, on the tails of this report, is that the CFPB will seek to ban class action waivers and mandatory arbitration clauses in consumer finance agreements.

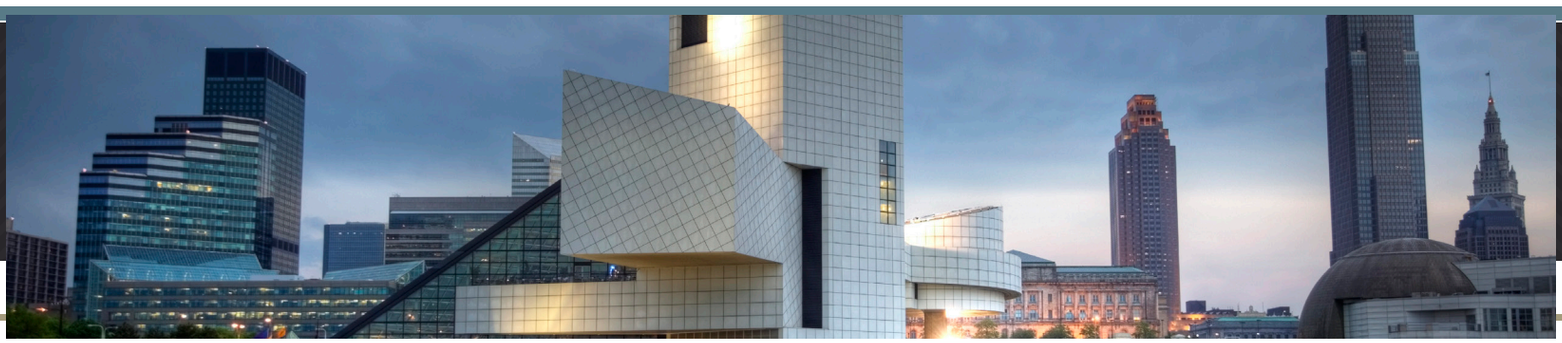
The Chamber of Commerce has already made clear that it will oppose any such ban...probably by filing a lawsuit. ◆

SPANGENBERG LAW FIRM

Spangenberg Shibley & Liber LLP
1001 Lakeside Avenue East, Suite 1700
Cleveland, Ohio 44114
877.976.7834 ssl@spanglaw.com
www.SpangLaw.com

Leave Blank for Address

facebook.com/SpangenbergLawFirm @SpangenbergLaw youtube.com/SpangLawFirm



A referral from a client or friend is the greatest compliment our firm can receive.
We are grateful for every one of these gestures and for the confidence you place in us by doing so.
From all of us at Spangenberg Shibley & Liber, we express our sincere appreciation. Thank you!

SPANGENBERG LAWYERS STEP UP FOR STUDENT TRIAL ADVOCACY COMPETITION

Spangenberg lawyer William Eadie was the Regional Coordinator of this year's American Association for Justice's Student Trial Advocacy Competition (aka STAC), in which 16 teams from 10 law schools competed to crown the regional champion.

As Regional Coordinator, Mr. Eadie recruited and prepared lawyers and judges to serve as mock-trial judges and jurors for the 29 trials taking place over four days of the event. When he was a law student, Mr. Eadie competed and went to Nationals in the same event.

Other cities also hosting regional events included Washington DC, New York, and Seattle. The winner of the event held here in Cleveland, Notre Dame Law School, will head to Nationals in Pittsburgh later this month.

The Spangenberg Law Firm sponsors the Regional as part of the firm's legacy of legendary trial lawyers like Craig Spangenberg, and to further AAJ's mission to inspire excellence in trial advocacy through training and education.

Spangenberg lawyers Stuart Scott, Michael Hill, Dan Frech, and Jeremy Tor all served as judges. You can find more pictures at *www.facebook.com/OhioRegionAAJSTAC*.

Mr. Eadie gives final instructions before the kick-off of the student competition.

The University of Akron School of Law team with The Honorable Robert McClelland (center) and Mr. Eadie (left).