

Lessons learned from public private partnerships in the counterfeit medicines arena

October 18, 2018

[Academy of Managed Care Pharmacy](#)

[Alaska Pharmacists Association](#)

[American Association for Homecare](#)

[American College Health Association](#)

[American Pharmacists Association](#)

[American Society of Health System Pharmacists](#)

[Arizona Pharmacy Alliance \(AzPA\)](#)

[Association for Accessible Medicines](#)

[Association of Nurses in AIDS Care](#)

[BioForward](#)

[Biotechnology Innovation Organization](#)

[California Life Sciences Association](#)

[California Pharmacists Association](#)

[California Society of Health-System Pharmacists \(CSHP\)](#)

[Colorado BioScience Association](#)

[Community Access National Network](#)

[Delaware Pharmacists Society](#)

[European Federation of Pharmaceutical Industries and Associations \(EFPIA\)](#)

[Healthcare Distribution Alliance](#)

[HealthCare Institute of New Jersey](#)

[Healthcare Leadership Council](#)

[The Hispanic Institute](#)

[Illinois Pharmacists Association](#)

[Institute for Safe Medication Practices](#)

[International AntiCounterfeiting Coalition](#)

[International Federation of Pharmaceutical Manufacturers and Associations](#)

[International Health Facility Diversion Association](#)

[Kidney Cancer Association](#)

[The Latino Coalition](#)

[The Life Raft Group](#)

[Maryland Pharmacists Association](#)

[Maine Pharmacy Association](#)

[Maine Society of Health-System Pharmacists \(MSHP\)](#)

[Men's Health Network](#)

[Minnesota Pharmacists Association](#)

[Missouri Pharmacy Association](#)

[National Alliance for Hispanic Health](#)

[National Alliance On Mental Illness](#)

[National Association of Chain Drug Stores](#)

[National Association of Boards of Pharmacy](#)

[National Association of Drug Diversion Investigators](#)

[National Association of Manufacturers](#)

[National Alliance of State Pharmacy Associations](#)

[National Biopharmaceutical Security Council](#)

[National Community Pharmacists Association](#)

[National Grange of the Order of Patrons of Husbandry](#)

[NeedyMeds](#)

[New York State Council of Health-system Pharmacists \(NYSCHP\)](#)

[North Carolina Association of Pharmacists](#)

[Oklahoma Pharmacists Association](#)

[Parenteral Drug Association](#)

[PDMA Alliance](#)

[Pennsylvania Pharmacists Association](#)

[Pennsylvania Society of Health-system Pharmacists](#)

[Pharmaceutical Industry Labor-Management Association \(PILMA\)](#)

[Pharmaceutical Security Institute](#)

[Pharmacist Planning Services Institute](#)

[PhRMA](#)

[RetireSafe](#)

[Spina Bifida Association of America](#)

[Texas Pharmacy Association](#)

[Texas Society of Health-System Pharmacists](#)

[United States Chamber of Commerce](#)

[University of New England College of Pharmacy](#)

[University of Texas at Austin College of Pharmacy](#)

[Vietnam Veterans of America](#)

[Virginia Pharmacists Association](#)

[Vermont Pharmacists Association](#)

[West Virginia Rx](#)

[WomenHeart](#)

PSM is one of many public private partnerships in the patient safety space.

- Perform much of the public documentation of counterfeit incidents.
- Conduct research faster than U.S. government agencies.
- Has the ability to operate without restrictions that constrain government agencies.

Publicizing successes and influencing outcomes

Internet pharmacy pioneer's licence reinstated, just days after it was suspended

Kris Thorkelson's Manitoba licence was pulled on same day his Canada Drugs reached tentative plea deal in U.S.

By Karen Pauls, CBC News | Posted: Dec 21, 2017 5:03 PM CT | Last Updated: Dec 21, 2017 5:14 PM CT



American prosecutors accuse CanadaDrugs.com, its CEO Kris Thorkelson, affiliated companies and associates of selling \$78 U.S. in unapproved and counterfeit cancer drugs to U.S. doctors. (CBC)

Thorkelson's company, CanadaDrugs, continues to hold provincial wholesale pharmacy licenses and a Canadian Federal manufacturing pharmacy license.

Terms of **pending** plea deal with U.S. Department of Justice for Kris Thorkelson

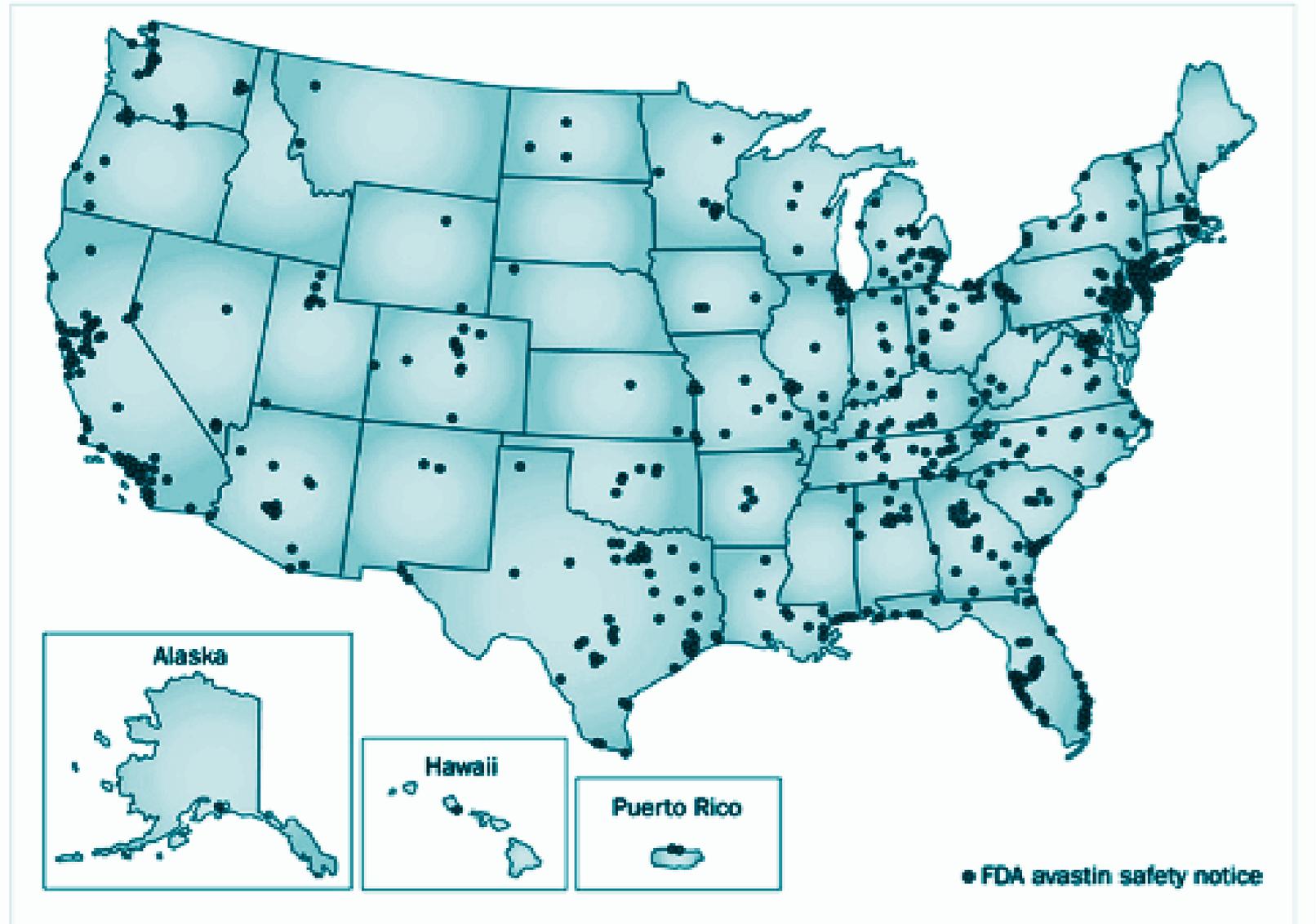
- Six months house arrest and four and a half years of probation;
- a \$250,100 fine; and
- Turn over records and cooperate in future investigations.

The plea agreement does not require him to:

- serve any jail time;
- surrender his pharmacy license;
- enter a guilty plea of selling counterfeit drugs.

He is not prohibited from holding any kind of pharmacy license or starting a new pharmacy business to export to America.

Figure 1: Visual depiction of a total of 949 FDA safety notifications that were sent to 932 physicians and/or clinics in 795 zip codes from 2012 to 2013.



Part of the FDA's Alert network that circulates alerts about drug recalls

**SAFE MEDS
ALERT**



Dietary Supplement Aimed at Weight-loss Recalled Due to Presence of Undeclared Sibutramine

October 17, 2018

This is a reprint of an FDA Alert.

Fat Burners Zone is voluntarily recalling 1 lot of Zero Xtreme, capsules to the consumer level. FDA analysis has found Zero Xtreme to be tainted with sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. The presence of Sibutramine in Zero Xtreme renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Risk Statement: Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and

FDA Contacts

For Adverse Events

[FDA Med Watch](#)

FDA's [Office of Criminal Investigations \(OCI\)](#)

800-551-3989

FDA FAX

800-332-0178

[Previous Alerts](#)

Materials to help educate consumers and healthcare professionals that interact with them.

Distribute our materials to consumers and pharmacists (we print them at cost for you!)



Factpack
9" x 6" spiral-bound book—63 pages



"Don't Believe the Lies"
8.5" x 14" poster



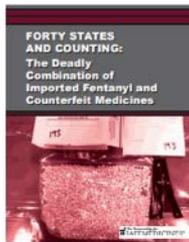
5-Ways/6-Things Bookmark
3.5" x 8.5" 2-sided informational bookmark



Bipartisan HHS/FDA
11" x 8.5" informational sheet



Fentanyl 101
folded 11" x 14" pamphlet



"Forty States and Counting"
Report
8.5" x 11" report—12 pages

Contact us to find out if we have materials about counterfeit drug investigations in your state:
editors@safemedicines.org

Re-share our materials on social media



Print materials:
editors@safemedicines.org

Every head of HHS and FDA for the last 18 years refused to certify the safety of drug importation.



Health & Human Services
(HHS) Secretary



"flaws and loopholes...make it impossible for me to demonstrate that it is safe and cost effective."

-Donna Shalala



"It's impossible for us to certify that these drugs are safe."

-Tommy G. Thompson



"The last thing we need is open borders for unsafe drugs in search of savings that can't be safely achieved. You can't improve competition and choice in our drug markets with gimmicks like these."

-Alex M. Azar II

Donna Shalala
(1993–2001)

Tommy G. Thompson
(2001–2005)

Michael O. Leavitt
(2005–2009)

Kathleen Sebelius
(2009–2014)

Sylvia Mathews Burwell
(2014–2017)

Alex M. Azar II
(2018–)

2000

2004

2008

2012

2016

2018

Mark Barr McClellan, M.D., Ph.D.
(2002–2004)

Margaret A. Hamburg, M.D.
(2009–2015)

Robert Califf, M.D.
(2016–2017)

Lester Mills Crawford, D.V.M., Ph.D.
(2005)

Scott Gottlieb, M.D.
(2017–)

Andrew C. von Eschenbach, M.D.
(2006–2009)



"Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient. Taking these drugs can pose a danger to consumers."

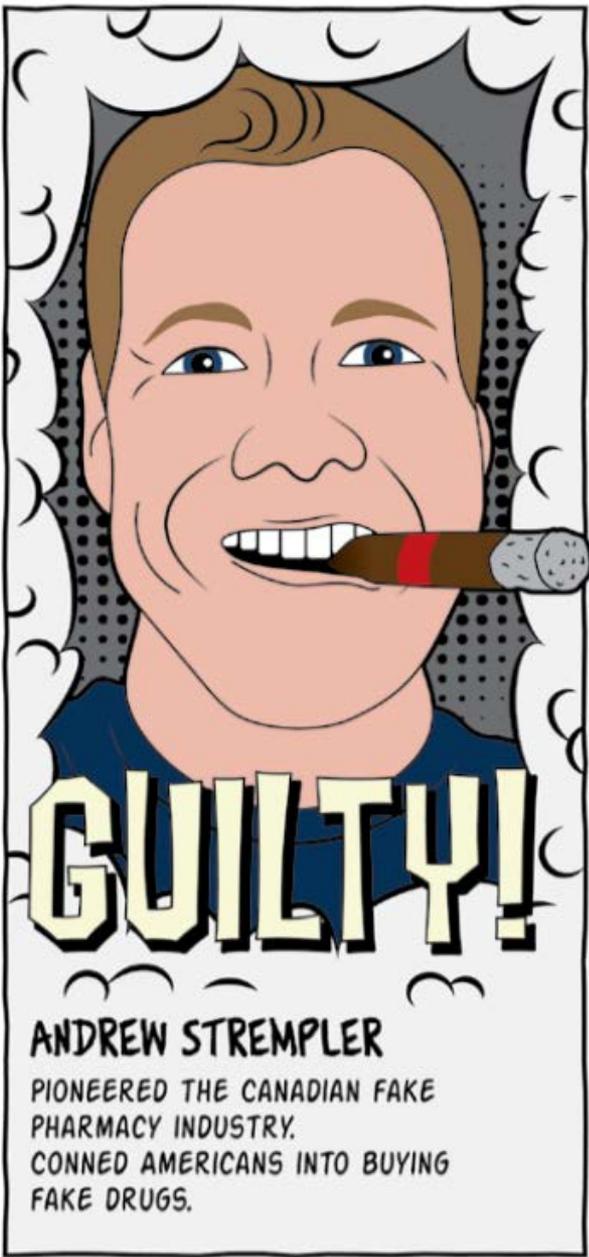
-Margaret A. Hamburg, M.D.



Commissioner of the
Food & Drug Administration

It's not a **Republican** or **Democrat** issue.
It's a **safety** issue.

To see all of the HHS and FDA quotes go to <https://safedrug.org/FDA-HHS>.

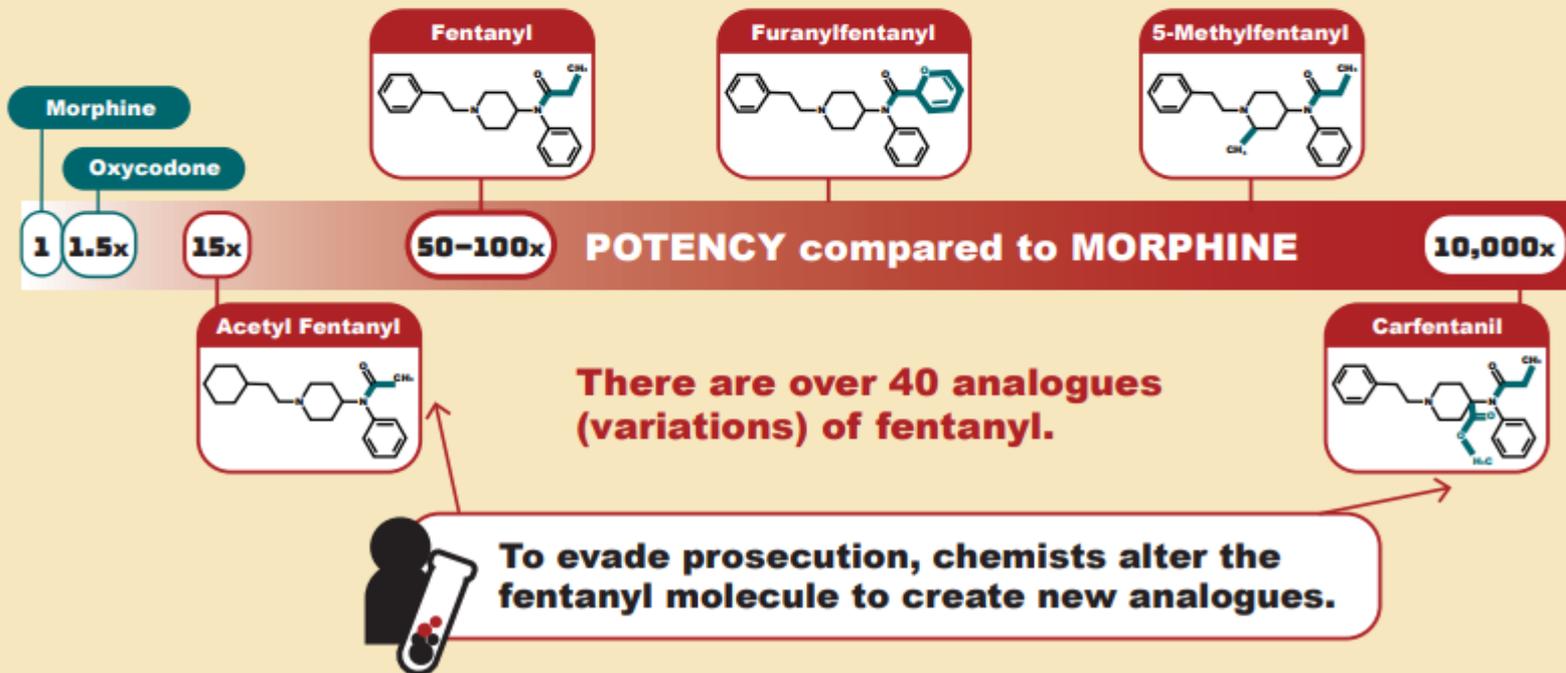


FENTANYL 101

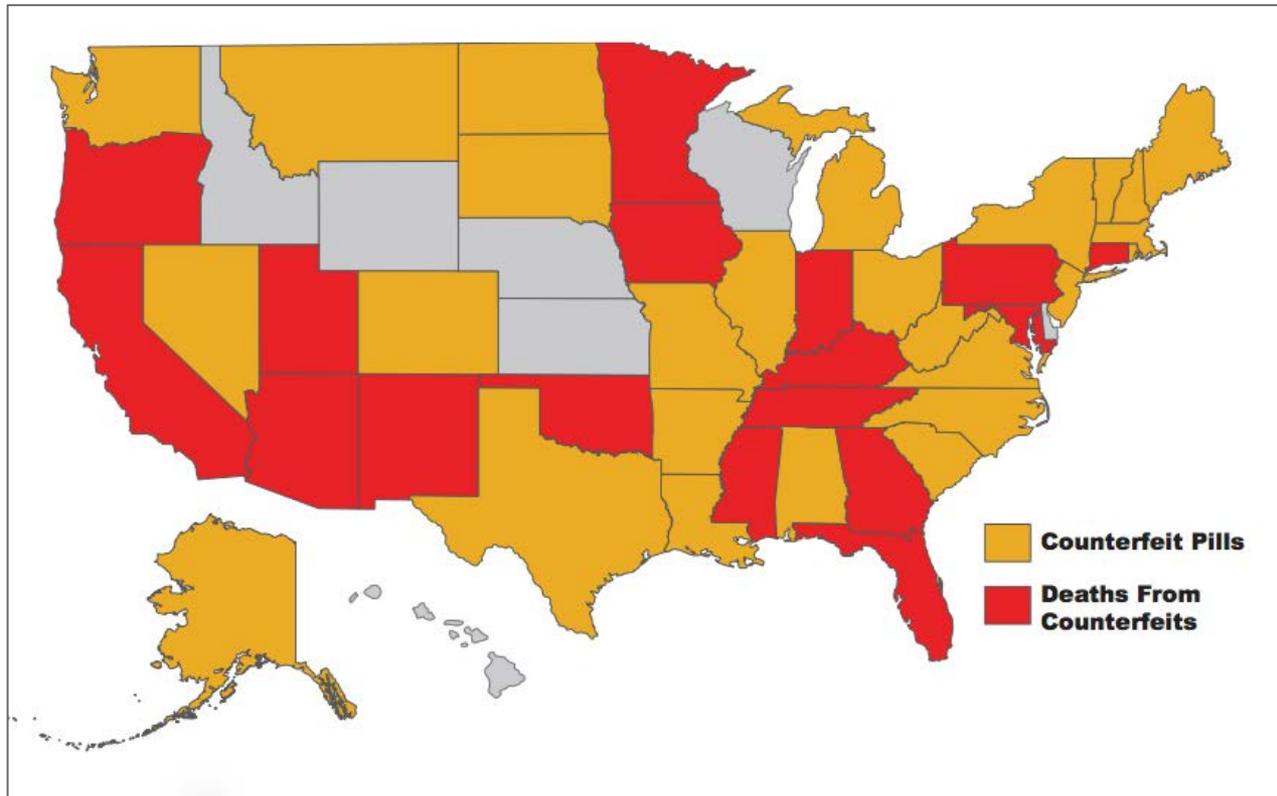
An introduction to the Fentanyl crisis in the U.S.

What are fentanyl and fentanyl analogues?

Fentanyl is a synthetic opioid that is 50–100 times more potent than morphine. Doctors prescribe fentanyl in medical settings, but drug traffickers manufacture black market fentanyl and sell it illegally.



Research: Fentanyl-laced counterfeit



Pills have been found in 43 states, with deaths reported in 22 – March 2018

Full report: “Forty Three States and Counting” at www.safemedicines.org

Tosh Ackerman of Aptos, CA

The evening of October 27, 2015, 29-year-old Aptos, California resident Tosh Ackerman took a benadryl and part of a Xanax pill to help him sleep. He never woke up, and his girlfriend found him dead the next day.

Investigation showed that Ackerman's Xanax was counterfeit. It contained a fatal dose of fentanyl.

Carrie is an active speaker to schools and the media. You can reach her at ToshStory@gmail.com



Teach consumers how to save money safely so they don't buy off the black market.

SAFE SAVINGS TIP

GENERIC LIPITOR

(atorvastatin)



 The Partnership for
SAFEMEDICINES.ORG®

47 of the 50 most frequently prescribed medications in the U.S. are available in cheaper generic form.

Americans **pay less** for most commonly prescribed generic medications than Canadians do.

Patient Safety Organizations (PSOs)

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs to improve quality and safety by reducing the incidence of events that adversely affect patients.

A secure place to improve quality and safety

The Patient Safety Act and Rule makes PSWP privileged and confidential. Subject to certain specific exceptions, Patient Safety Work Product may not be used in criminal, civil, administrative, or disciplinary proceedings.

It is usually de-identified, but can sometimes be identifiable health information subject to the same HIPAA (healthcare privacy) rules.

Thank you