Avoiding Rogue Internet Pharmacy Suppliers in the Effort to Improve Access to Medicines

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Learning Objective

• To discuss the benefits/risks of Internet pharmacy purchases to improve access to medicines
The Proposition

- Internet pharmaceutical purchasing represents a challenge to accepted practices of pharmacy and the integrity of pharmacy rules and regulations within jurisdictions.

- It is a disruptive force - it can be positive or negative.

- This debate affects patients, as well as their national governments, public and professional advocacy groups, and the pharmaceutical industry.

- Prompted regulatory bodies to reengage in policy making and to discuss important issues such as access to medicine.
Highlights

• Access to Medicines
• Online Pharmacy as a Disrupter
• Institutional controls
• Positives and Negatives of Internet Pharmacy
• FDA Key Points
• Brussel Principles
• Take-Aways
Access to Medicines Remains a Public Health Challenge

- Drug supply problems are a critical constraint for making progress in health outcomes within the spectrum of treatable diseases globally
- According to the World Health Organization about one-third of the global population does not have regular access to medicines
- In the United States, prescription drug prices continue to rise
- AARP reported from 2008 – 2016 – most popular brand-name drugs increased by 208% in the United States
Access to Medicines Remains a Public Health Challenge

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Enter the Disrupter: Online Pharmacy

• Online Internet pharmacies are websites that sell prescription medicines through the Internet and dispense the prescriptions through the mail

• About 4.7 million Americans purchase their prescription drugs through international online pharmacies

• Source: National Centre for Health Statistics at the Center for Disease Control
Internet Pharmacy Milestones

- The National Association of Boards of Pharmacy created the Verified Internet Pharmacy Practice Sites (VIPPS) in 1999
- VIPPS – a voluntary program for pharmacies to help consumers identify safe pharmacies
- By 2000, large retail pharmacies using the Internet
- Relative low value of Canadian dollar, lower prescription drug prices in Canada, and high cost of US medicine fostered the growth of Canadian online pharmacies targeting American consumers
- Establishment of credible website controls – e.g. PharmacyChecker.com and Canadian International Pharmacy Association

Internet Pharmacy is Popular in Rural Arizona

• Price is likely the main motivator for Internet pharmacy purchases

• Still, the convenience of Internet purchases is heightened in rural areas when the distance to a pharmacy may be greater than in urban areas

• 55 percent of the persons who purchase from Canadian Internet pharmacies live in rural areas in Arizona

• Source, Tim Smith, CIPA, July 2018
CANADIAN INTERNATIONAL PHARMACY ASSOCIATION (CIPA)
Celebrating 15 years serving millions of patients with safe and affordable maintenance medications, with a 100 percent perfect safety record

Who is CIPA?
CIPA is a Canadian association of licensed, retail pharmacies that sell Health Canada-approved pharmaceuticals and maintenance medications to individuals with a valid prescription. CIPA members also have relationships with regulated international pharmacies or inspected fulfillment centers that directly deliver medications to patients. Our member pharmacies have maintained a 100 percent perfect safety record, while serving about a million Americans each year, since CIPA was formed in 2002.

What does CIPA do?
We sell pharmaceuticals and maintenance medications made by the leading brand-name manufacturers for up to a 90-day supply, at prices 50-80 percent less than U.S. pharmacies. Some of the top prescription drugs purchased through CIPA member pharmacies include Plavix, to prevent blood clots after a heart attack; Zetia and Lipitor, to reduce cholesterol; Wellbutrin XL, to treat depression; and Prandin and Januvia, to treat diabetes. CIPA members do not sell controlled substances, narcotics or pseudoephedrine products.
# Brand vs. Brand

Manufactured by the same company at the same cost. Delivered to two different countries

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Canada</th>
<th>Percentage Discount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advair Diskus</strong></td>
<td>$1,102</td>
<td>$436</td>
<td>60%</td>
</tr>
<tr>
<td>Condition: asthma &amp; COPD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Crestor</strong></td>
<td>$519</td>
<td>$225</td>
<td>57%</td>
</tr>
<tr>
<td>Condition: high cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Premarin</strong></td>
<td>$451</td>
<td>$121</td>
<td>71%</td>
</tr>
<tr>
<td>Condition: estrogen therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Abilify</strong></td>
<td>$2,642</td>
<td>$645</td>
<td>76%</td>
</tr>
<tr>
<td>Condition: depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zetia</strong></td>
<td>$1,028</td>
<td>$259</td>
<td>75%</td>
</tr>
<tr>
<td>Condition: high cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Most Popular Medicines – CIPA 2018

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advair</td>
<td>Asthma</td>
</tr>
<tr>
<td>Januvia</td>
<td>Type 2 Diabetes</td>
</tr>
<tr>
<td>Spiriva Caps and Device</td>
<td>Chronic Obstructive Pulmonary Disease (COPD)</td>
</tr>
<tr>
<td>Entocort EC</td>
<td>Crohn's disease, Ulcerative Colitis</td>
</tr>
<tr>
<td>Crestor</td>
<td>Cholesterol</td>
</tr>
<tr>
<td>Zetia</td>
<td>Cholesterol</td>
</tr>
<tr>
<td>Flovent Inhaler</td>
<td>Asthma</td>
</tr>
<tr>
<td>Asacol</td>
<td>Ulcerative Colitis</td>
</tr>
<tr>
<td>Lialda</td>
<td>Ulcerative Colitis</td>
</tr>
<tr>
<td>Xarelto</td>
<td>Used to prevent blood clots</td>
</tr>
</tbody>
</table>
But Internet Pharmacy is Vulnerable to Fakes

- Profit opportunities through the Internet have fostered proliferation of “fake Internet pharmacies”
- Imposter sites that disguise themselves as legitimate pharmacies
- This is patently corruption - the abuse of entrusted power for private gain (Transparency International)
- Regulation and control of these “rogue” sites - complex to govern
What Do You See?

We Have a Global Wicked Problem

“One of the most intractable problems is that of defining problems (of knowing what distinguishes an observed condition from a desired condition) and of locating problems (finding where in the complex causal networks the trouble really lies). In turn, and equally intractable, is the problem of identifying the actions that might effectively narrow the gap between what-is and what-ought-to-be.” (Rittel & Webber, 1973)

Oregon Doctor Admits To Injecting Patients With Non FDA-Approved Anti-Wrinkle Treatments

July 6, 2018

A doctor in Oregon, Brenda Roberts, pleaded guilty in federal court to purchasing non-FDA-approved anti-wrinkle cosmetic injectables and using them on her clients. An affidavit in the case also states that she operated a rogue online pharmacy that distributed controlled substances to customers throughout the United States...

[...]

CSIP And LegitScript Report Shows Bad Effects Of Fake Foreign Pharmacy Websites

July 3, 2018

The Center for Safe Internet Pharmacies issued a report detailing the ease at which opioids are available for sale online. The research performed by LegitScript shows how shockingly simple it is to buy opioids and substances like fentanyl on the Internet...

[...]
Research Into Fake Online Pharmacy Prosecutions Finds Current Policies Do Little To Stop Them

May 11, 2018

A 2017 legal review conducted by Camille Guerra and Dr. Timothy K. Mackey predates the Canada Drugs prosecution, however it clearly illustrates the challenges faced by courts in effectively prosecuting illicit online pharmacies.

[...]

NABP Finds Fake Online Pharmacies Are Offering Fentanyl For Sale At An Alarming Rate

February 9, 2018

The National Association of Boards of Pharmacy (NABP) has just released their Internet Drug Outlet Identification Program Progress Report for February 2018. NABP has conducted an annual survey of Internet drug outlets for the last nine years, and this year it is finding that fake online pharmacies are rushing to get on the fentanyl bandwagon.

[...]
Pennsylvania Pharmacist Sentenced For Passing Imported, Misbranded Drugs Off As FDA-Approved

November 2, 2017

Four years after pleading guilty in 2013, a Pennsylvania pharmacist has been sentenced to 6 months of home detention and three years probation after pleading guilty to charges of conspiracy to smuggle foreign drugs in the United States and money laundering.

[...]

NH Couple Plead Guilty To Importing Hundreds Of Thousands Of Fake Pills

September 20, 2017

NH couple pleaded guilty to importing hundreds of thousands of fake pills from India and selling them via the internet to customers throughout the U.S...

[...]
Costa Rican Man Stands Accused Of Running Fake Online Pharmacy

September 7, 2017

Quesada was originally indicted in October 2015. He allegedly used his websites to sell medication to unsuspecting U.S. patients that were unaware they were buying misbranded and counterfeit prescription drugs manufactured in India.

[...]

National Boards Of Pharmacy Finds Only 4.2% Of Online Pharmacies Are Safe

August 25, 2017

The National Association of Boards of Pharmacy (NABP) has just released their Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: August 2017, outlining the current state of fake online pharmacies that sell to U.S. patients.

Out of 11,688 Internet drug outlets reviewed, the NABP found that 11,142 (95.8%) were "operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy standard practices."

[...]
Alliance For Safe Online Pharmacies Poll Finds Many Unaware Of Dangers Posed By Fake Online Pharmacies

July 20, 2017

A new survey conducted by the Alliance for Safe Online Pharmacies (ASOP) has found that a majority of Americans are in the dark when it comes to dangers posed by unlicensed online pharmacies.

[...]

Counterfeit Prescription Drugs A Problem In Canada & Australia

July 20, 2017

The National Post reports that since October 2015, Health Canada has stopped almost 10,000 packages containing counterfeit prescription drugs at the Canadian border. New reports from a 2010 incident reveal that counterfeit drugs ended up in 260 pharmacies and four hospitals in Australia. Patients were protected by a thorough hospital pharmacist who noticed “it was grittier than normal.”

[...]
1. Customer places order
Customer orders prescription drugs from a rogue Internet pharmacy in Russia. The pharmacy’s website uses servers in Brazil and China.

2. Payments processed
Customer payments for the prescription drugs are processed by a bank in Azerbaijan.

3. Prescription drugs sent
Prescription drugs are shipped from India to the customer.
Bad Medicine

• Advances in technology are making it harder to distinguish authentic pharmaceutical products from falsified or substandard ones.

• Advent of Internet pharmacy is creating opportunities for better access to medicines but also the global expansion of falsified/substandard medicines if sufficient controls are not in place.

• The WHO estimates that about 25 percent of drugs consumed in poor countries are falsified or substandard:
  • High cost of medicines
  • ↑ demand ↓ supply/shortage
FDA WARNING ABOUT ROGUE ONLINE PHARMACIES
SOME SITES SELLING UNAPPROVED OR COUNTERFEIT MEDICINES
Law & Policy Lagging Behind

• Rogue online pharmacies that engage in the sale of medicines particularly controlled substances (CS) without a prescription pose a threat to public health and patient safety

• Many patients addicted to opioids have purchased them through the Internet

• A study by Mackey et al. in 2017 identified illegal online pharmacies through an analysis of tweets on Twitter

• Found 1778 posts marketing the sale of controlled substances - 90 percent included hyperlinks to online sites for purchase

• Contravenes Ryan Haight Online Pharmacy Consumer Protection Act prohibits the sale and marketing of controlled substances directly to consumers online
Are Offenders being Punished?

• A 2017 legal review conducted by Camille Guerra and Timothy K. Mackey underscored challenges of prosecuting rogue online pharmacies

• Found “current legal tools and regulatory policies do not effectively deter this highly profitable criminal activity”

• If punishment risks are low and potential for profit is high – we can expect that illicit pharmacies will continue to thrive

• Issue of prosecution more complex when dealing with international jurisdictional issues
What is Real and What is Fake?

• Credible Internet pharmacy websites are listed on websites such as the National Association of Board of Pharmacies (NABP) and PharmacyChecker.com
• Still, the NABP has a list of about 11,000 sites it deems as suspect
• Many of the “fake” pharmacies try to pose as websites from Canada
• They can easily shut down and “reinvent” their websites so hard to catch
Rogue Pharmacy Operations are Complex

“According to federal agency officials, piecing together rogue Internet pharmacy operations can be difficult because they may be composed of thousands of related websites, and operators take steps to disguise their identities”

Source: US Government Accountability Office (GAO) “Internet Pharmacies: Most Rogue Sites Operate from Abroad, and Many Sell Counterfeit Drugs” February 27, 2014
• Rogue Internet pharmacies do not declare the contents of packages, in violation of customs laws
• Hide drugs in different types of packaging; in bottles of lotion and in tubes of toothpaste.
• Breach federal laws, including those related to fraud and money laundering.

• “The ease with which operators can set up and take down websites also makes it difficult for agencies to identify, track, and monitor rogue websites and their activities, as websites can be created, modified, and deleted in a matter of minutes”
FDA Website Warnings

“Signs of a Rogue Online Pharmacy

• Beware of online pharmacies that:
  • Allow you to buy prescription medicine without a valid prescription from your health care provider.
  • Do not have a U.S. state-licensed pharmacist available to answer your questions.
  • Offer very low prices that seem too good to be true.
  • Send spam or unsolicited email offering cheap medicine.
  • Are located outside of the United States or ship worldwide.
• These pharmacies often sell medicines that can be dangerous because they may:
  • Have too much or too little of the active ingredient you need to treat your disease or condition.
  • Not contain the right active ingredient.
  • Contain the wrong or other harmful ingredients.”

Source: https://www.fda.gov/ForConsumers/Consumerupdates/ucm048396.htm
FDA Signs of a Safe Online Pharmacy

“There are ways you can identify a safe online pharmacy. They:

• Require a valid prescription from a doctor or another licensed health care professional.
• Are licensed by your state board of pharmacy, or equivalent state agency. (To verify the licensing status of a pharmacy check your state board of pharmacy.)
• Do not appear on the National Association of Boards of Pharmacy’s “List of Not Recommended Websites.” (Just because the online pharmacy does not appear on this list does not mean it is safe.)
• Have a U.S. state-licensed pharmacist available to answer your questions.
• Are in the United States, and provide a street address.

Another way to check on a website is to look for the National Association of Boards of Pharmacy’s (NABP) Verified Internet Pharmacy Practice Sites™ Seal, also known as the VIPPS® Seal.

Source:
https://www.fda.gov/ForConsumers/Consumerupdates/ucm048396.htm
Recognizing that,

- the World Health Organization estimates that over two billion people lack regular access to essential medical products (i.e. medicines, vaccines, and diagnostics), which is exacerbated by a lack of affordability and local availability;
- the Internet has served as a disruptive force to traditional industry in the practice of pharmacy and trade in pharmaceutical products, allowing for the international sale of medical products to patients with a prescription;
- failure to regulate the sale of medical products over the Internet, including failure to differentiate between legitimate online pharmacies and rogue websites, poses a major public health risk; and
- governments are neglecting their human rights obligations when their populations do not have adequate access to affordable healthcare, including access to medical products.
We affirm the following principles relating to the sale of medical products ordered for personal use over the Internet:

BP1. Access to affordable medical products is a fundamental component of the right to health.

BP2. Patients with a prescription should be able to use the Internet to order safe, quality and affordable medical products for personal use.

BP3. National and regional legislation, regulation, and enforcement policies and actions should not prevent and/or deter patients with a prescription from importing safe, quality and affordable medical products for personal use.

BP4. Governments, international organizations and non-governmental organizations should promote a competitive online marketplace for safe and quality medical products in order to protect and facilitate affordability and access for all populations.

BP5. Policies that affect online access to medical products should aim to be evidence-based and patient-centered, including consideration of the fact that affordability and local availability can be significant barriers to access.

BP6. National, regional and international regulatory efforts should promote guidelines and best practices to ensure that online pharmacies are a reliable and safe source of medical products for patients. They should also identify and, through enforcement actions, sanction those online marketplaces engaging in the intentional sale and distribution of falsified and substandard medical products, as defined by the World Health Organization, as well as the sale of medical products to patients without a prescription.

BP7. Internet intermediaries, such as domain name registries, advertising networks, payment processors, financial institutions as well as physical and electronic mail and delivery services should not misuse their commercial power to disrupt online access to safe, quality and affordable medical products.
What I Know for Sure: Online Pharmacy is Here to Stay

• Patients will seek ways to purchase their medicines efficiently and cost-effectively through the Internet

• Efforts underway to solidify the safety of Online Pharmacy

• Patients need to be educated about how to use Internet safely for their pharmaceutical needs

• There are legitimate Internet pharmacies and their related partners that are seeking to ensure patients understand the difference between credible and rogue websites

• The promise of the Brussels Principles
Thank You

Thanks also to Gabriel Levitt and Tim Smith