Medication on Demand –
Online Drug Sellers
A Discussion of Legal and Patient Safety Issues

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Conflicts of Interest/Disclosure
- Presenter is the Senior Manager for the .Pharmacy program, which is a service referenced in this presentation
- Presenter declares no other potential conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria

Pharmacist Learning Objectives
- At the conclusion of this program, the pharmacist will be able to:
  - Describe the role of the National Association of Boards of Pharmacy® (NABP®) and its relationship to the US state boards of pharmacy
  - Identify the problems found by NABP and others with regards to online drug sellers, including legal issues of concern
  - Identify potential solutions to help patients be safe when shopping for medications online, including the .pharmacy top level domain

Technician Learning Objectives
- At the conclusion of this program, the pharmacy technician will be able to:
  - Describe the role of the National Association of Boards of Pharmacy® (NABP®) and its relationship to the US state boards of pharmacy
  - Identify the problems found by NABP and others with regards to online drug sellers, including legal issues of concern
  - Identify potential solutions to help patients be safe when shopping for medications online, including the .pharmacy top level domain

Pretest Question
- What is the estimated return on a $1,000 investment in the sale of counterfeit drugs?
  A. $2,000
  B. $5,000
  C. $10,000
  D. $30,000
See: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4105729/

Pretest Question
- How many illegal drug outlet websites are currently selling Rx meds online?
  A. Between 1,000 to 5,000
  B. 5,000 to 10,000
  C. 10,000 to 20,000
  D. 30,000 to 35,000
What Is NABP?

- **NABP** is a **nonprofit, international, impartial professional organization** that supports its member boards of pharmacy in protecting the public health.
- **Member boards of pharmacy** include the 50 United States, four US jurisdictions, nine Canadian provinces, Australia, New Zealand, and the Bahamas.

What Is NABP?

- **Services for Member Boards**
  - **Examinations**
    - North American Pharmacist Licensure Examination® (NAPLEX®)
    - Multistate Pharmacy Jurisprudence Examination® (MPJE®)
    - Foreign Pharmacy Graduate Equivalency Examination® (FPGE®)
    - Pharmacist Assessment for Remediation Evaluation™ (PARE™)
  - **Licensure**
    - Electronic Licensure Transfer Program® (e-LTP®)
    - Verified Pharmacy Program® (VPP®)
    - NABP Clearinghouse – licensure disciplinary data

What Is NABP?

- **Other Services**
  - **Accreditation**
    - Verified Internet Pharmacy Practice Sites® (VIPPS®)
    - Veterinary Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®)
    - NABP e-Advertiser Approval Program™
    - Verified-Accredited Wholesale Distributors® (VAWD®)
  - **Consumer Protection**
    - AWAR® Prescription Drug Safety Program – prescription drug abuse prevention program

What Is the Mission of NABP and its Members?

- **NABP** supports its member boards of pharmacy in their efforts to regulate pharmacists and pharmacies for the purpose of protecting public health
- **Public health protection** is the foundation for all NABP programs and services

How Do US Boards of Pharmacy Regulate Internet Pharmacies?

- Must comply with same **licensure** requirements as all pharmacies
- Must comply with same pharmacy **practice** requirements as all pharmacies
- Must **register** in nearly all states in which they ship prescription drugs
- Must follow additional requirements in some states
  - Eg, must display certain information on its home page, or must be VIPPS-accredited.

Other Requirements for Internet Pharmacies?

- **US Food and Drug Administration (FDA)**
  - If a pharmacy is **compounding** for clinic use or doctor’s office, then registration as an “outsourcer” is required and manufacturing standards must be met.
- **US Drug Enforcement Administration (DEA)**
  - If dispensing **controlled substances**, then certain requirements must be followed:
    - Registration with DEA
    - Reports to DEA regarding prescription controlled substances dispensed
    - Certain information must be disclosed on the website
    - DEA also requires that at least one face-to-face medical evaluation take place prior to a prescription for controlled substance being issued (with certain exceptions).
INTERPOL’s Operation Pangea seized **20.7 million fake and illicit medicines** and shut down over 2,400 illegally operating websites in 2015.

- Worldwide sales of counterfeit medicines in 2014 were approximately **US $75 billion**, a 90% rise in five years.
- WHO estimates between **100,000 and 1 million people** die from using counterfeit drugs annually.

**NABP Website Review Findings**

As of March 31, 2016:
- NABP has reviewed and verified its assessment of 11,154 drug sites.
- 10,685 (95.8%) found to be in conflict with state and federal pharmacy laws and are listed as Not Recommended.
- 261 (2.3%) designated as reviewed, i.e. lack egregious violations but have not satisfied NABP certification requirements.
- 208 (1.9%) are accredited or approved through VIPPS, Vet-VIPPS, e-Advertiser, or .pharmacy.

**98%** of Not Recommended sites in 2015 dispensed prescription medicine with **no valid prescription**.
Most Not Recommended sites in 2015 lacked accountability

- 65% posted no physical address on the website
- 56% registered their domain names anonymously

In more than 50% of cases, medicines purchased over the internet from illegal sites that conceal their physical address have been found to be counterfeit.*

*World Health Organization

Substances Found In Bad Medicine

- Antifreeze
- House paint
- Floor wax
- No medicine

• 1 in 5 US shoppers purchased medicine online in 2015*

• Only 12% of Americans are aware of the possibility that drugs ordered online may be counterfeit*

*Center for Safe Internet Pharmacies (CSIP)

Illegal sites returned in organic search results
Patient Advocates Attempt Change

- NABP Verified Internet Pharmacy Practice Sites (VIPPS) Accreditation Program
- FDA BeSafeRx Campaign
- INTERPOL Operation Pangea
- LegitScript
- Alliance for Safe Online Pharmacies
- EU Falsified Medicines Directive
- Center for Safe Internet Pharmacies (CSIP)
- International Institute of Research Against Counterfeit Medicines (IRACM)

Current Tools in Use - Seals

- **Seals/badges/logos**
  - NABP VIPPS, Vet-VIPPS, and e-Advertiser seals
  - EU common logo
  - LegitScript seal of approval

Current Tools in Use - Verification Sites

- **Verification sites**
  - LegitScript – “Is it Legit?”
  - NABP VIPPS and e-Advertiser lists
  - FDA BeSafeRx – Provides state government sites to check pharmacy licensure
  - CSIP - “Verify before you buy”

IRCAM recently issued “12 Golden Rules”: Things you need to know before buying medications online

Here are 3 of the 12:

**Do's and don'ts**

1. Use a verified online pharmacy for your prescription drugs.
2. Ask your doctor or pharmacist for recommendations.
3. Avoid websites with unsolicited offers.
4. Be cautious of “cheaper than the local pharmacy” propositions.

**Fraudulent use of NABP seal**

Fake pop-up when seal is clicked to create appearance of legitimacy

NABP keywords are used to generate results in organic search
NABP Efforts to Address Illegal Online Sales of Medicines

1999
• VIPPS

2004
• Vet-VIPPS

2010
• E-Advertiser

2014
• .pharmacy

VIPPS – Verified Internet Pharmacy Practice Sites

• Launched in 1999 after Internet drug sales skyrocketed and reports of illegal activity and patient harm surfaced.
• Pharmacies must meet 19 criteria:
  – Application and document review
  – Policies and procedures review
  – License verification
  – Website review
  – On-site survey

Vet-VIPPS – Veterinary Verified Internet Pharmacy Practice Sites

• Launched in 2004 after reports of illegal veterinary drug sales, consumer fraud, harm to pets.
• Pharmacies must meet 19 criteria (similar to VIPPS)
  – Application and document review
  – Policy and procedure review
  – License verification
  – Web site review
  – On site survey

E-Advertiser Approval Program

• Launched in 2010, this program evaluates Internet advertisers that offer only limited pharmacy services or other prescription drug related services online.
• Advertisers must meet 11 standards.
  – Application and document review
  – License verification
  – Web site review
A Tool to Win the Fight

- **.Pharmacy** is a secure and trustworthy verified Top-Level Domain (TLD), like .edu or .gov.
- In 2012, with the support of a global coalition of stakeholders, NABP applied to the Internet Corporation for Assigned Names and Numbers (ICANN) to become the registry operator of the new .pharmacy TLD.
- NABP received approval from ICANN and launched .pharmacy in 2014.
- .Pharmacy is dedicated to patient safety.

NABP .Pharmacy Public Service Announcement

...image...

Governance of the .Pharmacy TLD Program

Overseen by executive board

- Composed of members of the global coalition that supported .pharmacy.
- Defines strategy, oversees standards, and appoints members to the advisory committees.
- Includes representatives from NABP, NAPRA, FIP, .Pharmacy Registrant/Supporter Advisory Committee, and Regulator Advisory Committee, as well as a non-voting secretariat.

Distinct from verification sites and certification badges: the "seal of approval" is built into the website’s URL.

Easy for consumers to spot a legitimate pharmacy: look to the right of the dot.

Stakeholders

NAPBA, ASOP, ANORP, Pfizer, Lilly, FIP, and CalPharm have joined forces to support the initiative.

216 NABP certified online pharmacy companies representing over 34,000 brick-and-mortar stores in the United States.*

*As of 2016, data from various pharmacies in the U.S. including internet, mail-order, hospital, and community pharmacies.
All Roads Lead to .Pharmacy

. Pharmarcy Application Process

- Application → Assessment → Approval
- Renewal ← Monitoring ← Registration

. Pharmarcy Evaluation Specifics

- If an applicant is US based, the application will be assessed by NABP and US states.
- If applicant is based outside of the US, NABP will collaborate with and defer to the applicable authorities for adherence with standards.
- Discussions with/agreements established with regulatory authorities for NABP to perform assessments
  - Australia, Canada, Great Britain, Hong Kong, Ireland, and Spain

Ongoing Compliance Monitoring

- Approved registrants of .pharmacy domain names will be monitored for continued compliance with standards.
- Domain names within .pharmacy will be subject to suspension or revocation upon the violation of the terms and conditions set forth in the registration agreements.

Domain Name Use Cases

1. Making .pharmacy your primary web address
2. Operating .pharmacy and old sites in parallel
3. Creating .pharmacy landing pages
4. Redirecting .pharmacy domain to old web address

- Applicants are screened
- Credentials are verified
- Proposed website content is evaluated
- Legal compliance in all applicable jurisdictions is confirmed
- Accordance with standards is ensured
Use Case #1
Making .Pharmacy Your Primary Web Address

- Most effective long-term way to build online reputation, web presence, and SEO
- Demonstrates commitment to patient safety

Use Case #2
Operating .Pharmacy and Old Sites in Parallel

- Use both .pharmacy and previous domain and associate each with its own identical website
- Maintain primary website while building recognition for .pharmacy domain

Use Case #3
Creating .Pharmacy Landing Pages

- Complement your primary website
- Quickest, easiest, least expensive way to attract attention of search engines

Use Case #4
Redirecting .Pharmacy Domain to Old Web Address

- Simple, inexpensive immediate solution
- Previous domain name remains primary

Search engines already recognize NABP programs for US and Canadian pharmacies

Bing  Google  YAHOO!
Consumer Education

- Fundamental goal is to educate consumers to recognize .pharmacy as the valid designation for a legitimate pharmacy or medication-related entity.
- “Look to the right of the dot.”
- Increase awareness of rogue online drug sellers masquerading as pharmacies.
  - Dangers of counterfeit drugs and buying prescription drugs without a prescription.
- As consumer recognition increases, more pharmacies and pharmacy-related businesses will be willing to undertake the application process throughout the world.

Current Status of .Pharmacy

- **Fortune 500 Buy-in:** Six Fortune 500 organizations registered at least one .pharmacy domain in 2015, including CVS, Target, Rite Aid, Express Scripts, and Merck
  - 380 domain names approved
  - 241 .pharmacy domain names registered

### .Pharmacy Domain Name Registrations

- **241** Registered Domains
  - 1 School
  - 5 Professional
  - 4 Manufacturers
  - 35 Resources
  - 185 Pharmacies

- **medlife.pharmacy**
- **bioplus.pharmacy**
- **www.futrell.pharmacy**
What’s Next for .Pharmacy?

- Creating a **safer Internet** environment for patients
  - Creating global collaborations
    - NAPRA
    - European Union “Common Logo”
    - National Standards Setting Partnerships (by country)
  - Creating partnerships with other verified TLDs
  - Creating search engine solutions

International Stakeholder Outreach

- .Pharmacy current availability in US, Canada, Great Britain, Ireland, Hong Kong, Australia, and Spain
- Applications received from US, Canada, Saudi Arabia, Great Britain, Hong Kong, Germany, and Austria
- Global outreach including speaking engagements and stakeholder meetings in China, Canada, Italy, Germany, Holland, France, Great Britain, Philippines, Belgium, Argentina, Ireland, Singapore, Los Angeles, Washington DC, and New York City

.Pharmacy: The Future of Health Care Delivery

Electronic health care (EHR; telemedicine; e-prescribing)

Pharmacy as health care destination

Increased scope of practice for pharmacists

Posttest Question

- Which one of these is **not** a recommended resource for patients and providers?
  A. LegitScript's [www.legitscript.com](http://www.legitscript.com)
  B. ASOP’s [www.safeonlinerx.com](http://www.safeonlinerx.com)
  C. NABP’s [www.safe.pharmacy](http://www.safe.pharmacy)
  D. CIPA’s [www.cipa.com](http://www.cipa.com)

Posttest Question

- If a website uses the words “Canada” or “Canadian” in its URL address (eg, [www.canadadrugs.com](http://www.canadadrugs.com)), this means that it is a licensed Canadian pharmacy and it is safe for patients.
  A. True
  B. False

Posttest Question

- If a website ends in the top level domain name .pharmacy (eg, [www.rxstore.pharmacy](http://www.rxstore.pharmacy)), this means that it has been verified by the National Association of Boards of Pharmacy.
  A. True
  B. False
Conclusion

- Illegal online drug sales – dangers are numerous and deadly
- Variety of ways to remain safe – VIPPS, Vet-VIPPS, e-Advertiser, .pharmacy
- Success of .pharmacy will not be measured by the number of domain names registered, but by the assistance provided to patients and the level of recognition and trust placed in the .pharmacy domain.

Questions?

- For further information, view our websites at nabp.pharmacy or safe.pharmacy
- Email Marty Allain at mallain@nabp.pharmacy or Melissa Madigan at mmadigan@nabp.pharmacy