

## Medication on Demand – Online Drug Sellers

A Discussion of Legal and Patient Safety Issues

Marty Allain, JD  
.Pharmacy Senior Manager  
National Association of Boards of Pharmacy



## 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

See <http://www.safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf>



## 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® (FPGEE®)
    - Pharmacist Assessment for Remediation Evaluation<sup>SM</sup> (PARE<sup>SM</sup>)
  - **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<sup>CM</sup>
    - Verified-Accredited Wholesale Distributors® (VAWD®)
    - Durable medical equipment, prosthetics, orthotics, and supplies accreditation (DMEPOS)
  - **Consumer Protection**
    - AWA<sub>RxE</sub>® 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?

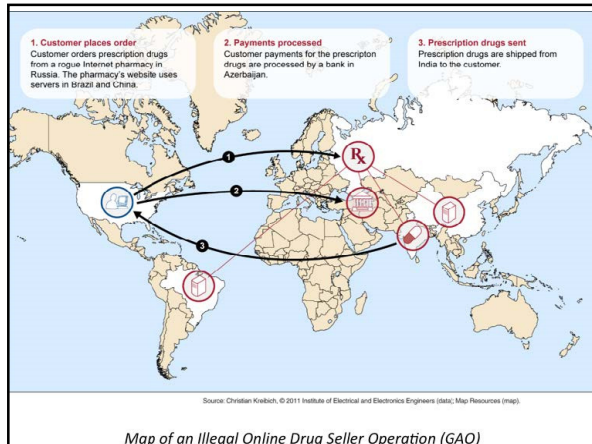
- Must comply with same **licensure** requirements as all pharmacies
- Must comply with same pharmacy **practice** requirements as all pharmacies
- Must **register** in nearly all states in which they ship prescription drugs
- Must follow additional requirements in some states
  - Eg, must display certain 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
- 

The online sale of unregulated and unsafe drugs is widely recognized as a **global public health threat**

### 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, ie 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**

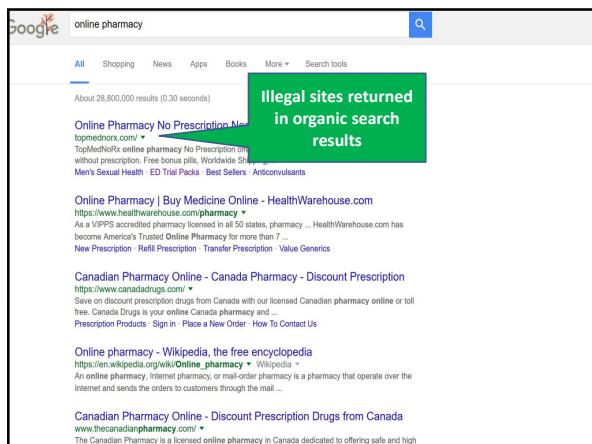


- **1 in 5** US shoppers purchased medicine online in 2015\*



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

*\*Center for Safe Internet Pharmacies (CSIP)*

online pharmacy

About 28,800,000 results (0.30 seconds)

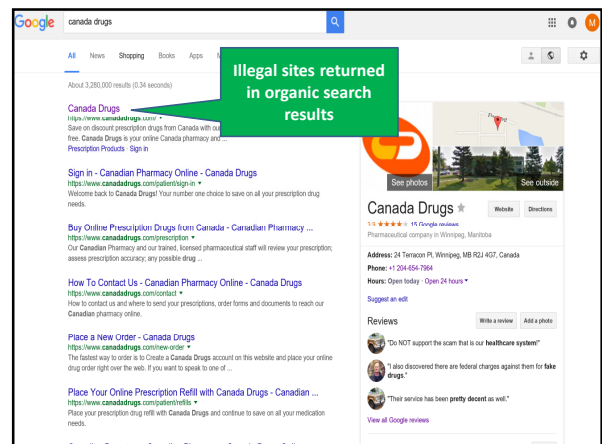
**Illegal sites returned in organic search results**

Online Pharmacy No Prescription Med...  
<https://www.healthwarehouse.com/pharmacy>  
 As a VIPPS accredited pharmacy licensed in all 50 states, pharmacy... HealthWarehouse.com has become America's Trusted Online Pharmacy for more than 7...  
 New Prescription - Refill Prescription - Transfer Prescription - Value Generics

Canadian Pharmacy Online - Canada Pharmacy - Discount Prescription  
<https://www.canadadrugs.com/>  
 Save on discount prescription drugs from Canada with our licensed Canadian pharmacy online or toll free. Canada Drugs is your online Canada pharmacy and...  
 Prescription Products - Sign In - Place a New Order - How To Contact Us

Online pharmacy - Wikipedia, the free encyclopedia  
[https://en.wikipedia.org/wiki/Online\\_pharmacy](https://en.wikipedia.org/wiki/Online_pharmacy) - Wikipedia  
 An online pharmacy, internet pharmacy, or mail-order pharmacy is a pharmacy that operate over the internet and sends the orders to customers through the mail...

Canadian Pharmacy Online - Discount Prescription Drugs from Canada  
[www.thecanadianpharmacy.com/](http://www.thecanadianpharmacy.com/)  
 The Canadian Pharmacy is a licensed online pharmacy in Canada dedicated to offering safe and high



canada drugs

About 3,280,000 results (0.34 seconds)

**Illegal sites returned in organic search results**

Canada Drugs  
<https://www.canadadrugs.com/>  
 Save on discount prescription drugs from Canada with our toll free. Canada Drugs is your online Canada pharmacy and...  
 Prescription Products - Sign In

Sign In - Canadian Pharmacy Online - Canada Drugs  
<https://www.canadadrugs.com/patient/sign-in>  
 Welcome back to Canada Drugs! Your number one choice to save on all your prescription drug needs.

Buy Online Prescription Drugs from Canada - Canadian Pharmacy ...  
<https://www.canadadrugs.com/compare>  
 Our Canadian Pharmacy and our trained, licensed pharmaceutical staff will review your prescription, assess prescription accuracy, any possible drug...

How To Contact Us - Canadian Pharmacy Online - Canada Drugs  
<https://www.canadadrugs.com/contact>  
 How to contact us and where to send your prescriptions, order forms and documents to reach our Canadian pharmacy online.

Place a New Order - Canada Drugs  
<https://www.canadadrugs.com/new-order>  
 The fastest way to order is to create a Canada Drugs account on this website and place your online drug order right over the web. If you want to speak to one of...

Place Your Online Prescription Refill with Canada Drugs - Canadian ...  
<https://www.canadadrugs.com/patient/refill>  
 Place your prescription drug refill with Canada Drugs and continue to save on all your medication needs.

Canada Drugs  
 1.8 4.4 14 Google reviews  
 Pharmaceutical company in Winnipeg, Manitoba  
 Address: 24 Tannock Pl, Winnipeg, MB R2J 4G7, Canada  
 Phone: +1 204-654-7664  
 Hours: Open today - Open 24 hours  
 Suggest an edit


Reviews  
 Write a review Add a photo

"Do NOT support the scam that is our healthcare system!"  
 "I also discovered there are federal charges against them for fake drugs!"  
 "Their service has been pretty decent as well."

View all Google reviews

## 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”

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

Here are 3 of the 12:

**Do's and don't's**


1. Do an online search to find out what the laws are in your country of residence.
2. For example, google the following: “Ministry of Health, country name + medications online”
3. Among the items at the top of the results list you'll find a link that leads to the official website of your country. You should consult this list.

**Do's and don't's**

1. Go to the site of the public health authority in your country of residence (e.g. ministry of health, national association of pharmacists).
2. If possible, enter the name of your country or region of residence.
3. Make sure that the address (URL) of the website in question appears on the list of authorized online pharmacies (when using a search engine, preferably use copy and paste to avoid typos).

**Do's and don't's VERIFY**

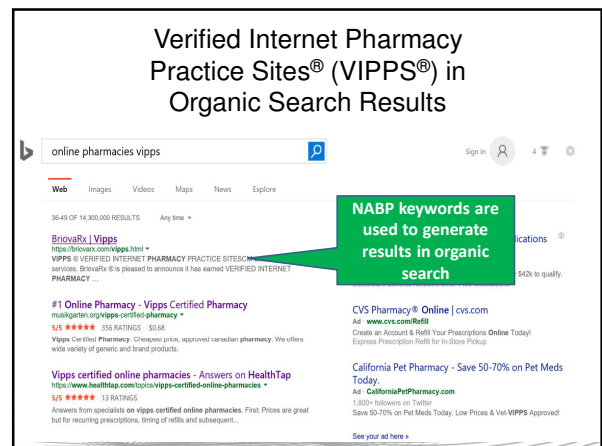
1. The site address (URL) which must be located in your country of residence (e.g. Germany, regular telephone numbers, as well as call routing services).
2. The phone number which must be in keeping with the phone numbers in your country (e.g. (34)4247990). Beware of call routing services.
3. The presence of the flags of various countries, as a likelihood means that the site sells to customers worldwide.
4. Make sure that you're asked to supply a doctor's prescription – providing of drugs that buying prescription drugs online is illegal in your country.




**Fraudulent use of NABP seal**

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

## Verified Internet Pharmacy Practice Sites® (VIPPS®) in Organic Search Results



**NABP keywords are used to generate results in organic search**



**FEDERAL TRADE COMMISSION**  
PROTECTING AMERICA'S CONSUMERS

News & Events » Press Releases » Operators of Phony Doctor Certification Program and Misleading Health and Lifestyle Websites Settle FTC Charges

**Operators of Phony Doctor Certification Program and Misleading Health and Lifestyle Websites Settle FTC Charges**

FOR RELEASE  
June 21, 2016

**Tags:** Over-the-Counter Drugs and Devices | Bureau of Consumer Protection | Consumer Protection | Advertising and Marketing | Endorsements | Online Advertising and Marketing

SmartClick Media LLC, also doing business as Doctor Truusted, and its owner Robert Vizebecky, also known as Anderson, have agreed to settle Federal Trade Commission charges that their "Doctor Truusted" certification program misled consumers with bogus claims that the products sold on websites with its seal were evaluated by doctors using their medical expertise.

The defendants also have agreed to settle charges that several of their websites, such as betterlivingjournal.org, were deceptively formatted to appear to be independent lifestyle blogs or health-product review sites.

"Consumers should be able to rely on seals and certificates for accurate information on how products are tested and evaluated," said Jessica Rich, Director of the FTC's Bureau of Consumer Protection. "Unfortunately, in this case, they were completely misled by the sellers of the 'Doctor Truusted' program."

According to the FTC's complaint, between June 2013 and October 2015 the defendants marketed and sold the "Doctor Truusted" seal and certification program to websites that primarily offered health-related products and services, such as dietary supplements.

When consumers clicked on the seal, they were shown a pop-up box that displayed the "Doctor Truusted" certificate, which stated that the products on the site were "carefully evaluated by an independent medical doctor who reviewed its medical information, claims, products, terms of service, and policies," and who deemed them "trustworthy and safe for purchase."

**Misleading seal from phony doctor certification program**

- Legitimate seals are easily replicable
- Phony certification programs offer misleading seals
- Legitimate verification sites pull users away from pharmacy site/transaction
- Disreputable verification sites promote illegal internet drug outlets
- Organic search results include illegal internet drug outlets
- All of this can be confusing to consumers:
- **Who do you trust?**

### 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

### .Pharmacy is the Solution


- **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




### Governance of the .Pharmacy TLD Program

Overseen by **executive board**

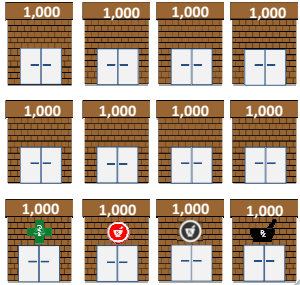

- Composed of members of the global coalition that supported .pharmacy
- **Defines strategy, oversees standards**, and appoints members to the advisory committees
- Includes representatives from NABP, NAPRA, FIP, .Pharmacy Registrant/Supporter Advisory Committee, and Regulator Advisory Committee, as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



### Stakeholders



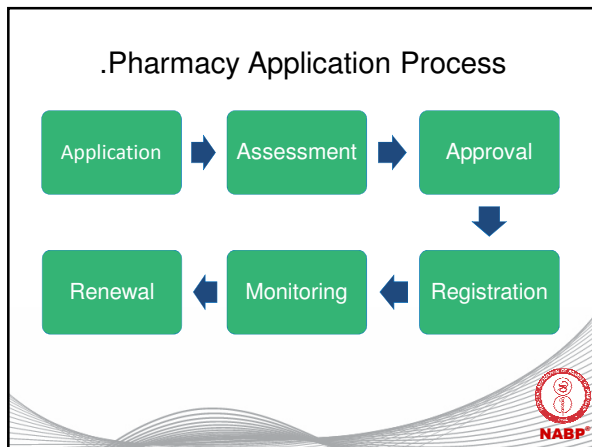

**216** NABP certified online pharmacy companies representing over **34,000** brick-and-mortar stores in the United States\*

\*69,000 in-state licensed pharmacies in the US including chain, community, hospital, nuclear, compounding facility, LTCF, and other. (Number excludes mail order/express dispensing.)



- 
- ✓ Applicants are **screened**
  - ✓ Credentials are **verified**
  - ✓ Proposed website content is **evaluated**
  - ✓ Legal compliance in all applicable jurisdictions is **confirmed**
  - ✓ Accordance with standards is **ensured**



- ### 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.

- ### .Pharmacy 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

- ### 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




### 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



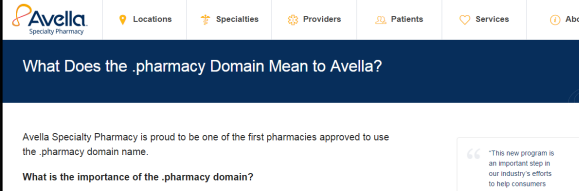
### Use Case #2 Operating .Pharmacy and Old Sites in Parallel




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



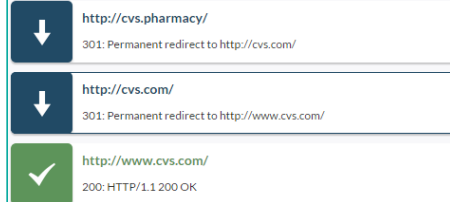
### Use Case #3 Creating .Pharmacy Landing Pages



- **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



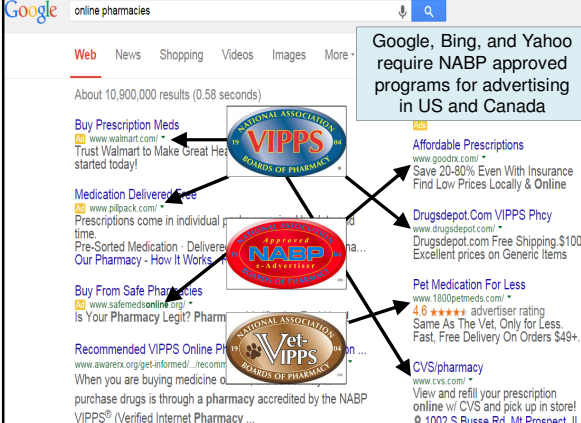
↓	http://cv.s.pharmacy/	301: Permanent redirect to http://cv.s.com/
↓	http://cv.s.com/	301: Permanent redirect to http://www.cv.s.com/
✓	http://www.cv.s.com/	200: HTTP/1.1 200 OK

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

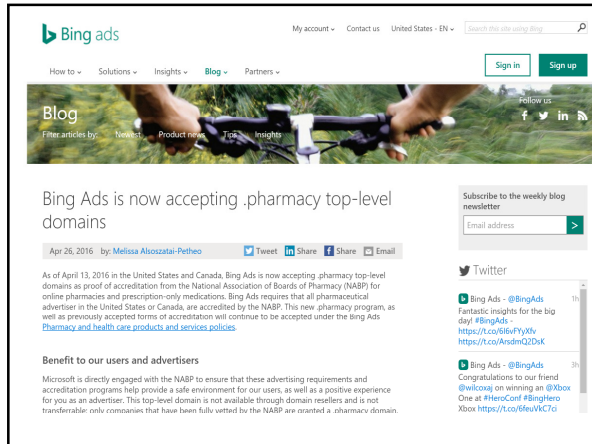


## Search engines already recognize NABP programs for US and Canadian pharmacies






Google, Bing, and Yahoo require NABP approved programs for advertising in US and Canada



### 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.



- **118.5 million** TV audience impressions
- **90.9 million** English radio impressions
- **13.9 million** Spanish radio impressions



Learn more about ordering medication safely online at [www.safe.pharmacy](http://www.safe.pharmacy)



### 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	5	4	8	35	185
School	Professional	Manufacturers	Resources	Boards	Pharmacies




### 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

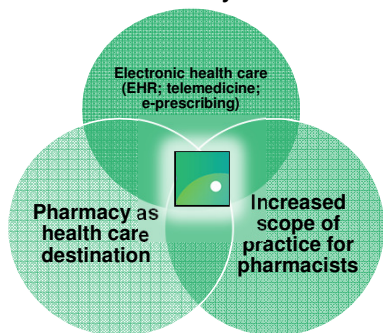


### International Stakeholder Outreach

- .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



### 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.safeonlinex.com](http://www.safeonlinex.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](http://nabp.pharmacy) or [safe.pharmacy](http://safe.pharmacy)
- Email Marty Allain at [mallain@nabp.pharmacy](mailto:mallain@nabp.pharmacy) or Melissa Madigan at [mmadigan@nabp.pharmacy](mailto:mmadigan@nabp.pharmacy)

