The risks and benefits of the Online Pharmacy Market

By Roger Bate

Summary

Perhaps five percent of American adults purchase medicines from online pharmacies. This figure amounts to millions of people who are looking for convenience and cheaper prices, spending well over a billion dollars a year.

Safety is likely among the most important risks involved in buying medicines online. Websites can sell fake medications while stealing consumers' identity.

Over the past decade my research team has purchased drugs from online pharmacies, each time evaluating the processes, products, sites, and those who credential them.

While the US Food and Drug Administration does not certify online pharmacies, it funds one of several third-party organizations that do certify them. We found that credentialing of sites was the single most important determinant of whether the site was likely to always sell good quality medicines. Credentialed sites, whether in the US or overseas, sold us good quality medicines. Some non-credentialed sites sold us fake medicines.

From a policy standpoint these findings conflict with what the pharmaceutical and pharmacy industries would want. Both maintain that buying from outside the US is dangerous and that one can only be safe buying FDA-approved US-sourced medicines. The result is obfuscation and misleading statements from both industries and their

respective front organizations. This is harmful to both patients and the reputations of both businesses.

The FDA oversees drug quality and informs consumers that it is illegal to personally import medicines into the US. However, on its websites, it acknowledges what nearly everyone who buys online knows to be true, that if you import less than 90 days supply of medicine for personal use the law is not enforced.

FDA does not have jurisdiction of overseas sites and hence cannot actively support them, but it could at least discuss the evidence on credentialing that is in the peer review literature. To not do this is a detriment to its goal of helping US patients access good quality affordable medicine.

Introduction

The reason Americans want to buy medicine over the internet is primarily due to high drug prices in America. To understand why prices are high in the US means understanding the economics of drug pricing.

Periodically, Tufts University publishes its latest analysis of drug research, and in 2014 it found that it costs roughly $2.5 billion to make a new drug. The average time a drug takes from discovery, to laboratory testing and clinical trials, is more than a decade, and the vast majority of targeted chemicals never make it to the market. The Tufts analysis allows for the costs of the failures as well as the successes.

These figures are roundly attacked by health/anti-capitalist activists as being far too high, and in Washington DC the debate rages (at least amongst pharma nerds) for days.

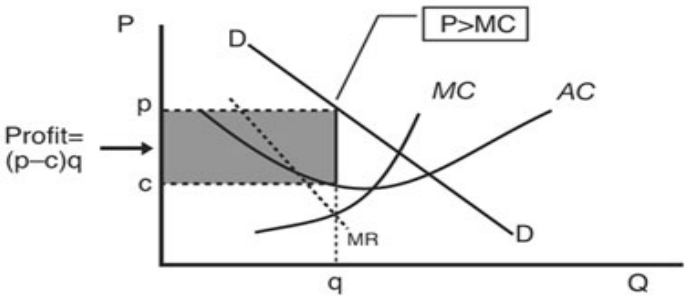
Drugs are not unique goods, but they are unusual, and the way they are produced and the costs of that production mean that there are always fights regarding how to price drugs, which is the real debate.

Pricing of pharmaceutical drugs is not a simple function of supply and demand: production is extremely highly-regulated, which affects costs greatly; and access to supply (particularly for certain drugs) is widely perceived as a moral issue.

Prices need to be higher in industrialized countries in order for pharmaceutical companies to recoup the costs of production, as well as to provide an incentive for further innovation. The costs of research and development must be shared across the myriad drug markets, with the richer paying significantly more than the poor, and those in the middle contributing more than the poorest. The goal of distinguishing between markets is ultimately to reconcile patents–which are necessary for innovation–with the affordability and accessibility of these drugs in poor countries.

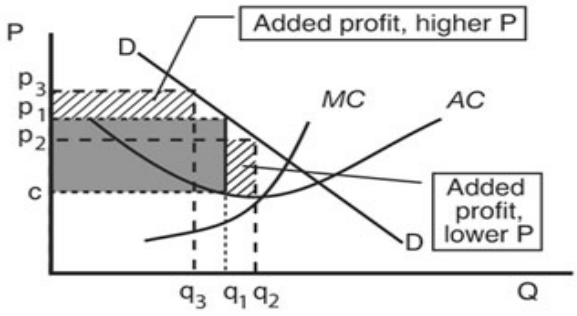
Figure 1 illustrates a situation in which a firm with some market power (facing the downward-sloping demand curve DD) is trying to find the one price that will maximize profits. Given the market demand and cost conditions in that market, the firm will maximize profits at that output (*q*) where marginal costs equal marginal revenue (MC=MR). At this output, profits (the solid rectangle) will be as large as possible, but *p* will be greater than MC.

FIGURE 1
SINGLE-PRICE MARKET



SOURCE: Robert B. Helms, "Pharmaceutical Industry Economics: Pricing and Investment Incentives" (presentation, AEI-Brookings Joint Center for Regulatory Studies, Washington, DC, May 17, 2007).

FIGURE 2
MULTIMARKET PRICE DISCRIMINATION



SOURCE: Robert B. Helms, "Pharmaceutical Industry Economics: Pricing and Investment Incentives" (presentation, AEI-Brookings Joint Center for Regulatory Studies, Washington, DC, May 17, 2007).

While it costs hundreds of millions of dollars to produce the first pill of a new drug, the marginal cost (MC) of producing additional pills is very low. Therefore, a traditional pricing system that charges consumers the marginal cost of the drug would not take into account the high R&D costs that the firm incurred. But when producers in such industries can charge different prices to different people, they can expand production and reach a wider section of the market.

Figure 2 illustrates this differential pricing system (by assuming that companies can isolate and keep separate different groups of buyers, represented by the demand curve DD). Simply put, those who are able and willing to pay more (i.e., the wealthier) are charged p_3, while those who can or will only pay less (i.e., the poorer) are charged p_2. If this strategy is successful, and those receiving the lower prices cannot resell to those willing to pay more, then the company will get higher profits than it would by setting a single price.

Figure 2 is an oversimplification of the real market, but studies show that this form of differential pricing leads to a more socially efficient outcome. In the context of the pharmaceutical market, differential pricing allows pharmaceutical companies to produce more drugs than would be possible in a single-price system, thus giving patients in developing countries greater access to life-saving drugs.

Profits in the pharmaceutical context do not merely serve to fill wallets for shareholders: they allow R&D to be sustained and even expand. The price discrimination model allows middle- to high-income countries to bear most of the R&D costs, while affording low-income countries greater access than otherwise to the safe, effective drugs they need.

However, differential pricing of drugs has numerous opponents. Many Americans are upset that they pay more for medicines than people in other rich countries do, and many health activists are annoyed that the poor pay more than the cost of production for HIV/AIDS medicines. Both groups believe the pharmaceutical industry is accruing excess profits at their expense. No doubt sometimes the pharma industry prices its products poorly, but both in theory and practice differential pricing is both equitable and efficient.

Case Studies: Some apparently high prices and why they make sense

The above explains why one should differentiate product prices between patients with income disparities (in practice this can be difficult within each country, but broadly across nations it is easier to achieve). However, the health benefit of the product should also inform its pricing. Perhaps a fair comparison is between Sovaldi and Lipitor. The first cures Hepatitis C, while the latter lowers cholesterol and hence the risk of heart problems. The first requires one pill to be taken each week for 12 weeks, the latter is a daily regimen effectively required forever. Although there are 3.5 million Americans with Hep C, there are tens of millions who might require a statin like Lipitor.

One would therefore expect Sovaldi to be priced at a far higher level than Lipitor to be worth the investment in its discovery – it has fewer patients to target, it is a cure, so once the regime is finished there is no future market, and it takes almost no time and effort for the patient to be treated. And that is what we found, before Lipitor went off patent its cost was hundreds of dollars a month, whereas Sovaldi's cost is $84,000 for a 12 week treatment. We make no comment on whether these respective prices are equitable or efficient, just that one would expect pricing in this fashion.

Imagine we discovered a product (at great expense –tens of billions of dollars) that cured lung cancer with one pill. The benefit to humanity would be enormous, but would insurers be prepared to pay an equitable price of perhaps a million dollars for that pill? Probably not. And we see this with antibiotics, arguably the most important health discovery of all time. Yet since profits made from these products are so low, none are made in the US anymore.

Differential pricing based on wealth – an idea easier in principle than practice

It is quite straightforward for a drug company or wholesaler to price a product efficiently for the mean income level of a nation, however, it is far harder to price efficiently across a nation. Most people do not have the mean average income. Very few Americans could actually pay $84,000 out of pocket for Sovaldi, and while insurance systems (and Medicare and Medicaid) mean that most people are likely to be covered in an emergency, not everyone will be covered. So many of the uninsured or underinsured

are unable to take advantage of differential pricing within the US. So they should be able to seek cheaper prices elsewhere. For decades seniors and others would take buses to Canada to buy cheaper medicines due to Canada's price controls. Today and for the past decade that practice has switched to the online purchases.

Buying Online

Starting in 2008 we sampled five medicines from myriad web sites and repeated buying these medicines in three subsequent samplings. The first peer review paper was published in the scientific literature[1], simply assessing the quality of the products bought and relating that to the type of site that sold those products. We continued sampling and began analyzing the price data and other socio-economic factors.

My colleagues Ginger Zhe Jin from the University of Maryland and Aparna Mathur from the American Enterprise Institute and I published a research paper[2] that assessed the quality of medicines purchased from online pharmacies based on the type of certification those online pharmacies possess. Furthermore, to better understand the demand side of the online pharmacy market, we surveyed Americans who purchase medicines from online pharmacies to see if certification provides consumers with information they use to reduce the risk that they will buy fake medicines online.

The FDA advises consumers to avoid foreign based websites and only purchase from websites in the US that have been approved by the National Association of Boards of Pharmacy. However, there are at least four certification agencies that verify the credentials and business practices of online pharmacies: the NABP, CIPA (a Canadian pharmacy association), LegitScript.com and PharmacyChecker.com. By definition, NABP and LegitScript.com only approve US websites, CIPA only approves Canada-based websites, and PharmacyChecker.com covers websites operating in the US, Canada, and other countries.

We classified websites approved by the NABP and LegitScript.com as Tier 1, websites certified by CIPA and PharmacyChecker.com as Tier 2, and other websites without these certifications as Tier 3. Most Tier 2 and Tier 3 websites were registered outside the U.S.

Of the 328 samples that we purchased online and were delivered, all passed a Raman spectrometry test that verified authenticity except for 8 samples of Viagra purchased from Tier 3 websites. Of all the samples we were able to test and authenticate, Tier 2

[1] Assessing Website Pharmacy Drug Quality: Safer Than You Think?
PLOS One: August 13, 2010 http://dx.doi.org/10.1371/journal.pone.0012199
[2] In Whom We Trust: The Role of Certification Agencies in Online Drug Markets
The B.E. Journal of Economic Analysis & Policy, 2013, vol. 14, issue 1, pages 111-150

websites were 49.2% cheaper and Tier 3 websites were 54.8% cheaper than Tier 1 websites.

To better understand the demand side of the online pharmaceutical market, we designed a survey that was distributed by the group RxRights—a group concerned with the price of pharmaceuticals and access to them in the U.S. Among the 2,522 people who responded to the survey, 61.5% said that they purchase drugs online and mostly from foreign websites, citing cost savings as the primary reason. Of those that shop online, 41% said that they check with a credentialing agency when deciding where to make their purchases.

The study, then, shows that certification agencies do provide useful information for foreign websites and for consumers who purchase medicines online.

Furthermore, while the FDA is justified in warning consumers against the dangers of purchasing from rogue websites, our findings suggest that a blanket ban on all foreign websites—which currently exists, but is enforced mostly for large purchases and for purchases of controlled substances—may deny consumers substantial savings from purchasing medicines from foreign websites that are certified by third parties.

Vested pharmaceutical and pharmacy interests, either ignored the findings, or in a few instances tried to undermine them (below I discuss the role such groups play in undermining access to cheaper medicines). The criticism took many forms, from the personal and scurrilous to the more serious and relevant. I was asked by a journalist from the Associated Press whether, as had been alleged by a domestic pharmacy association, I received funding from the Canadian pharmacy business or organizations like CIPA or pharmacychecker.com (I never have). Others suggested I basically screwed up the research and that the online sites knew who I was and hence only sent me good products. This is extremely unlikely, and certainly so in the original purchases, because back in 2008 I was unknown on the topic. For the thesis to hold that I was a “known” entity we should see better performance after the initial purchase (when I was certainly unknown), yet we do not, the performance of products is virtually identical.

In an attempt to follow up and ascertain whether the situation has changed, and avoiding possible name awareness, my team recently (May 2016) procured a further 125 medicines from 25 websites. We were able to procure from 22 sites that we had procured from before. Five tier 1 and 11 tier 2 (all of which had been procured from before), of the remaining 9 websites of tier 3, three were new sites, and six were procured from before. As before the only fakes received were from tier 3 sites and again for Viagra, none of the other medicines failed raman spectrometry. The quality assessments were therefore almost exactly the same as before. Tier 2 and tier 3 sites were even cheaper relatively than before. Tier 2 sites 59% cheaper than tier 1 and tier 3 sites 63.3% cheaper than tier 1.

This leads me to the same but perhaps more urgent conclusion than before. Buying from credentialed overseas sites (tier 2), provides a similar degree of protection against poor quality medicines as tier 1, but at a far lower cost. Unfortunately, the political environment hasn't changed so education of possible users is the same as it was before. Only the more savvy e-users are buying for sites selling good medicines.

There is one obvious caveat to the conclusions of this research. We only bought five branded medicines due to the nature of the testing with raman spectrometry, so we did not analyze the wide variety of generic medicines available on the internet. And as our other research indicates (see www.safemedicines.net), some (non-OECD) generic makers cut corners and sometimes make substandard products. Additionally, as patients desire new medicines that are not small-chemically produced varieties but expensive biologics and their near generic equivalents "biosimilars", underinsured folks will become even more desperate to find cheaper alternatives. It would therefore be useful if some independent group were to undertake an evaluation of the generic products available from tier 1, 2 and 3 sites to assess whether our conclusions of branded products holds for generics. Eventually an assessment of biologics and biosimilars makes sense too.

Why don't more underinsured folks buy online?

Some people are undoubtedly averse to breaking the law, even if they know that the law is not enforced. But more people are probably worried about the safety of what they buy. But why are they so scared? The empirical evidence is quite clear from our research (which is the only peer review research on the topic), yet fear persists, even about credentialed pharmacies. And the reason for this is due to the efforts of the pharmaceutical and pharmacy industries and those they support.

The evidence is wide-ranging and deep that these industries have subtly and not so subtly misled the public, sometimes aided by elected representatives of US government.

Before internet sales became standard, industry realized arguments based on fear would sway consumers. As the Wall Street Journal noted as far back as 2003: "drug companies have found that the specter of bogus medicine is a forceful lever for moving public and policy-maker opinion in the U.S. against imports. Counterfeits may be a growing problem, but so far, the documented risks pale next to the rhetoric where imports are concerned."[3]

Industry-backed campaigns involve the following: fan the flames of fear, obfuscate the data that exist, present historic data now known to be false, prevent positive policy change through donations to political leaders and where possible draft rules to benefit insiders.

[3] http://www.wsj.com/articles/SB106418061476794700

1. Misinformation campaigns

Caution is warranted when buying online, but misleading the public into believing that buying online is always dangerous is unacceptable. Yet it is easy to achieve by subtle and not so subtle use of accurate data.

Assessing that there are 10,000 online sellers (the exact number doesn't really matter, it maybe 60,000), and then accurately stating that only a hundred or so are proper pharmacies, demanding prescriptions and operating inside US, means it is easy to say that over 98% of web sellers break the law by selling to US patients. Interests use this "truth" to then obfuscate by claiming that because sites that encourage personal importation act illegally it must also follow that they are a danger, with no evidence to back this up. I can find no evidence that a credentialed site sent dangerous products over the internet to patients.[4]

From a patient perspective, it is the dozens, maybe hundreds of web sellers that are legitimate pharmacies in their own nations, complying with all domestic laws, and selling price-capped medicines, that patients should want to find. It is simple to help people find these sites, if one wants to.

2. Lack of testing and use of biased studies

One of the reasons that our research is the only peer reviewed work on internet drug quality is because those promoting fear as the best reason to prevent importation probably suspects that if they did proper studies, they too would find that most of the medicines work. This reality is even alluded to by one of the key filters for information – the founder of Legitscript. John Horton told Politico that he : "believes perhaps the single biggest reason neither the FDA nor the pharmaceutical industry has put much effort into testing is that they're worried that such tests may show that the drugs being sold by many so-called rogue pharmacies are by and large chemically indistinguishable from those sold by approved pharmacies."[5]

We conducted our stratified sampling as described above. Probably the most surprising thing we found was that even the sites not demanding prescriptions and in some instances without physical addresses we could identify, usually sent good quality medicines. This is rational for most sites since they want repeat business and consumers can easily switch to another site if their purchases are obviously flawed.

[4] Some internet companies, such as Canadadrugs.com have been implicated in selling medicines wholesale to doctors that turned out to be bogus, but that is a different operation (and even then harm has not been established).

[5] http://www.politico.com/magazine/story/2014/12/pharma-spam-113562_Page2.html#ixzz4Fe3pB4mw.

3. The biggest meme

One study by Pfizer the innovator of Viagra, may have led to the most important and worst meme about internet drug supply. Probably the most widely cited statistic about internet pharmacies is simply untrue.

For example on numerous websites it reads “The World Health Organization estimates that more than 50% of prescription medicines that are bought from Internet sites that conceal their physical address are counterfeit”. But that’s not what the WHO’s website reads. It apparently claimed it once, but it has been removed, since it was never based on a WHO study. Coincidentally, Pfizer funded a study in 2004 that concluded 50% of Viagra purchased online is counterfeit[6]. Perhaps the WHO’s estimate was based on this Pfizer report. I’ve asked many people and no one seems to know.

Yet even though WHO withdrew support for the 50% figure, recently industry-funded groups (Alliance for Safe Online Pharmacies, the Coalition for Safe Internet Pharmacies), and Consumers League released this “fact sheet”[7]. It cites this WHO link [8] to show the 50% figure.

In a field with such a paucity of real data it is understandable that journalists cite whatever sources they can find, but groups actively engaged in the field, surely know that they are posting false statements, especially ones that benefit their agenda.

4. Conflating rogue with foreign.

The most important verification system is that of Legitscript, run by former George W Bush administration official John Horton. The pharma industry likes its work since it opposes all importation[9]. Legitscript classifies online pharmacies as Legitimate, Unverified, Unapproved and Rogue.

Interestingly, most pharmacychecker.com-verified international online pharmacies are not classed as “rogue”. Most fall under the classification of “Unapproved.” However, why one PC-approved or CIPA site is rogue and not unapproved is not explained. Examples:

1. Doctorsolve.com is Unapproved: https://www.legitscript.com/websites/doctorsolve.com/. PC and CIPA

[6] http://news.bbc.co.uk/2/hi/health/3696820.stm
[7] http://xtherisk.com/
[8] http://www.who.int/mediacentre/factsheets/fs275/en/
[9] https://www.techdirt.com/articles/20140824/07373128307/easydns-tries-to-balance-bogus-requests-to-take-down-legit-foreign-online-pharmacies-against-truly-rogue-pharmacies.shtml

2. CanadaDrugs.com is Rogue: https://www.legitscript.com/websites/canadadrugs.com/. PC and CIPA. Even though they are an extremely well run, safe, online pharmacy that only sources medications from the richest OECD countries. It's probably labeled "rogue" because of the wholesale business/counterfeit medication indictment.

3. YouDrugstore is unapproved: https://www.legitscript.com/websites/youdrugstore.com/. PC and CIPA

4. Buylowdrugs is unapproved: https://www.legitscript.com/websites/buylowdrugs.com/. PC only.

5. Adv-care.com is unapproved: https://www.legitscript.com/websites/adv-care.com/. PC only.

6. NorthwestPharmacy.com is rogue: https://www.legitscript.com/websites/northwestpharmacy.com/. CIPA and PC.

We bought from all of these sites and none sold us any bogus medicines.

The other issue with Legitscript is that since it gets a $5m grant from FDA, it is really not a consumer watchdog, but a branch of a government agency, and an agency that claims it has no oversight of pharmacies. In addition the NABP has a direct financial interest in preventing importation of medicine since its members lose from any importation at all. In that sense none of these groups can be considered independent. Additionally, groups that are apparently independent, such as the Association of Safe Online Pharmacies (ASOP) and Center for Safe Internet Pharmacies (CSIP) [10] are little more than fronts for the pharmaceutical industry.

It's not that they hide this, but they do pretend to be more independent of industry than they are. Worse still is their fast and loose attitude with speculation. The Associated Press journalist who asked me about my funding from pharmacychecker.com or CIPA was following an allegation he said was made by ASOP.

Conclusions

It is both efficient and equitable to tier prices across all of society, yet the insurance-run market and government programs fail to do this. Buying from the internet is a safety

[10] c. Obama Administration orders the formation of this non-profit: http://www.politico.com/magazine/story/2014/12/pharma-spam-113562_Page4.html#.V5fUC-grJPYB. ASOP and LegitScript are ex-officio members and according to sources "FDA goes to CSIP meetings and tells them what to do". So the Obama administration focused the formation of CSIP and CSIP spends money advertising on Google to use the LegitScript search to find legitimate online pharmacies.

valve due to these failures. Industry is overly concerned that allowing this safety valve will mean the end of high drug prices in US by allowing wholesale importation. This is a false concern. In the middle of this mess are millions of patients who cannot afford their medicines.