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An Analysis of the Prevalence of Over-the-Counter Painkiller Abuse

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Abstract

Pain, aches, fever, and discomfort are a part of the lives of many people. For most people, this pain can be managed using over the counter painkillers. OTC medications have a multibillion-dollar market. In the United States, patients can purchase as much of this medication as they desire to treat their pain. This medication can be easily abused and misused unintentionally. Every year, there are thousands of hospitalizations from misuse of these medications, and several cases of death. When taken incorrectly, these helpful medications can cause detrimental effects such as ulcers, kidney failure, and loss of liver function. The max daily dose is not much higher for these medications than for a prescription medication. The lack of regulations increases the prevalence of abuse. By analyzing restrictions in foreign nations, examining the avenues to abuse, and understanding how the medications work, the abuse can be limited.

Introduction

Over the Counter (OTC) painkillers play a significant role in the treatment of minor aches and pains. They provide quick relief in patients with symptoms such as fevers, headaches, muscle pain, and migraines. In the United States, 1.7 billion dollars was spent on Tylenol alone in 2020.¹ Access to this medication is readily available at several locations including pharmacies, grocery stores, and convenience stores. Unfortunately, there is little control and regulation over OTC painkillers. A person can purchase as much of the painkillers as they desire without any consultation from a trained medical professional.²

Several OTC medications have relatively low maximum daily doses which can be exceeded by taking less than just 6 tablets a day. Initially, a person will feel no harms from excessive consumption of OTC painkillers. However, prolonged abuse leads to liver damage, gastrointestinal bleeding, and increased risk of stroke. Every year, over 200,000 people are hospitalized due to over-the-counter painkiller abuse, and the annual deaths have increased to over 1,500 people.³ Countries are beginning to implement policies to educate and protect patients from abusing these medications. These changes have been shown to reduce deaths and long-term effects of abuse of these medications.

A primary reason over the counter painkillers are easily abused is the easy access we have to them in the United States. There are currently no restrictions on the purchase of acetaminophen, ibuprofen, naproxen, and other OTC products. For a patient who is not aware of the harms misuse can bring, the ease of purchase makes the medications seem harmless.

Methodology

Conducting research on the prevalence of over-the-counter painkiller abuse can be a challenging task. To ensure proper information was gathered, a variety of research articles, Drug Enforcement Agency publications, and testimony from medical professions was gathered. The research was exploratory to find out what is known about over-the-counter painkillers and what can be learned.

A clear process was followed when collecting data and continuing the research. First, an examination of how what medications fall into this classification was conducted. This dive into the classification of medications was done to see how easily the medications can be obtained and if there is any possibility they could be accidentally abuse. Primarily, drug classifications and schedules were found using public information provided by the Drug Enforcement Agency. Knowing what types of medications are over the counter is crucial before continuing with more elaborate investigations.

After knowing how the medications are classified, and the reasons for these classifications, it was time to examine the mechanism of action for the painkillers. This process is crucial for knowing how they affect bodily functions. The goal of this step is to find out which enzymes are being targeted, how they are being affected, and what change this brings about in the body. Usually, a change in the body sets off a series of changes that can eventually lead to a negative effect over time. The mechanism of action for the over-the-counter pain killers will give insight as to which organ systems may be impacted with long term use. When we know how a drug interacts with the body, we can determine the source of many side effects. This will explain why some of the pain killers affect one bodily function, but not others.

After we are aware of the of how over the counter painkillers affect the body, we will be able to explore the reported cases of abuse. These medications are common in the daily lives of many people. Because of this, many people are not aware that the medication can be easily abused. Cases of abuse are not limited to reported deaths. While there are deaths reported for each over the counter painkiller every year, we also want to examine the reported hospitalizations and search for instances of decreased quality of live due to abuse. This section of research will require the use of reported hospitalizations and inferences about short term abuse reported in research articles and journals.

The hospitalizations and side effects of the over-the-counter painkillers will be eye opening research. However, after this information has been found, the next step in our method will be to explore why deaths are still happening at an increasing rate. One of the big factors to be explored is the market for medication, specifically for over-the-counter painkillers. The market will be compared to previous years as well as to other countries around the world. This information will show how much people rely on these medications and how profit may contribute to the issue at hand.

A deep dive into facts and research will provide hard evidence, but testimony will provide experiences and real emotional effects from abuse of the medications. In this step of the methodology, we interviewed medical professionals as well as a patient to share their story about the impacts of over-the-counter painkillers. Their testimony would not be found in a published journal article, but it is valuable to understand the realness of the situation. The true stories often resonate with people strongly as they reinforce that this abuse happens in our own neighborhoods.

The total culmination of factual research, as well as the contribution of personal testimony, will provide the knowledge needed to understand the prevalence of over-the-counter painkiller abuse. Of course, dissecting the problem does not solve it. The final step of the research will be to investigate methods being implemented worldwide to reduce abuse. There is information available to the public about the possible effects of excessive abuse of over-the-counter painkillers in the United States, but exploring the

restrictions and purchasing limitations across the globe will give guidance to how we can solve the problem head on. The practices taking place in other countries may not be applicable but exploring them is necessary for developing a well-rounded solution.

Drug Classifications

There are many different types of medications that can be used to treat pain and discomfort. For several years, the restrictions on pain killers were not very intense. Medications were split into either prescription or non-prescription drugs. However, in 1970, the Drug Enforcement Agency implemented the Controlled Substances Act.⁴ This act further classified the different types of medications into different categories called Schedules. Each Schedule has different restrictions and regulations to prevent abuse and attempt to prevent addiction.

Schedule I

Medications in the Schedule I are deemed by the DEA to have no accepted medical use within the United States and have the highest potential of being abused if used. These drugs are not carried in the pharmacy as there is no approved use for them. Drugs in this classification include heroin, psychedelic drugs, MDMA, and lysergic acid diethylamide (LSD).

Schedule II

Schedule II medications still have a high risk for abuse by patients. However, they do have approved medical use. The medications under this classification are

heavily regulated to protect the patient. For example, prescriptions for these medications must be electronically sent to the pharmacy or hand-written by the prescriber. Only in the case of an absolute emergency can a Schedule II drug be prescribed orally. These drugs cannot have refills on their prescriptions, and a prescriber can only write a prescription for 90 days in advance. Medications in this Schedule include amphetamines, morphine, oxycodone, and hydrocodone.

Schedule III

As the trend suggests, Schedule III drugs have less potential for abuse than Schedule I and II drugs. This classification of medication can be prescribed orally, and a prescriber can prescribe up to five refills for the medication at a time. However, the prescription is only valid for six months before a new prescription is required.

Medications in this Schedule include ketamine, buprenorphine, and anabolic steroids such as testosterone.

Schedule IV and V

Schedule IV medications have a low potential for abuse but can lead to some psychological dependence if misused. This classification includes tramadol and zolpidem as well as benzodiazepines such as alprazolam, diazepam, and clonazepam.

Schedule V medications have the lowest risk for abuse and dependence. This classification includes pregabalin, lacosamide, and some medications with codeine.

Both Schedule IV and V medications can be prescribed with five refills that are valid for six months.

Schedule VI

All remaining prescription drugs are often classified as Schedule VI. This group of medications shows very little potential for abuse and physical dependence. This includes maintenance medications used to control things such as blood pressure, cholesterol levels, GERD, kidney function, and several other conditions. Prescriptions for these medications are valid for twelve months. A prescriber can write for unlimited refills in this twelve-month period, but insurance companies typically limit how often a prescription can be refilled.

Over the Counter

Any medication that can be purchased without a prescription falls into the category of over-the-counter medication. These medications can be bought in any pharmacy, with no restriction or limitation, and can treat symptoms such as pain, inflammation, cough, itching, and fever. In the United States, there is no restriction on how much and how often these medications can be purchased. While there is extremely low dependence for these medications, abuse is possible.

Many painkillers, such as opioids, fall into the controlled Schedules of medications. Because of this, patients need to receive a prescription from their prescriber to obtain these medications. To relieve the aches and pains from daily life,

millions of people turn to easily accessible over the counter painkillers to do the job. Since these medications are readily available and inexpensive, they are a great fit for minor aches and pains. Patients often do not realize that just because these medications are not controlled, there still is the possibility to abuse them over a long period of time.

Over the counter pain killers do not present immediate side effects when taken in excess quantities for a single dose. However, when patients take more than the recommended dose to treat their pain, their body becomes accustomed to this dose, and they tend to continue to take a high dose of the pain killer. Over time, they are consuming much more than the recommended daily amount and negative effects are soon to set in. For some patients, the illusion of a medication being unregulated makes them believe it cannot cause harm to them.⁵ This misconception is a driving factor as to why this unscheduled classification of drugs can be easily abused.

Mechanism of Action

Acetaminophen

Acetaminophen is commonly used to treat pain and aches, especially headaches. In the body, it is metabolized to p-aminophenol which is a compound that can cross the blood-brain barrier. From here, the chemical can act on proteins such as COX, opioid, and 5-HT₃ receptors.⁶ This interaction is what removes the sensation of pain. Acetaminophen is metabolized primarily in the liver. During the metabolism, a

toxic intermediate is produced. Fortunately, this chemical can be removed by the bodily supply of glutathione. Abuse of acetaminophen depletes the glutathione in the body, resulting in acute liver failure.

NSAIDs

A large family of pain-killing medications are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). This includes ibuprofen and naproxen. These medications also are COX inhibitors and can reduce fever and inflammation. Unlike acetaminophen, NSAID elimination from the body is not reliant on blood flow to the liver.⁷ An intermediate in the metabolism of NSAIDs causes a decrease in prostaglandins. In the body, this results in a reduction of renal plasma flow. When NSAIDs are abused, they lead to acute kidney failure.

Hospitalizations and Deaths

Patients tend to not abuse prescription medications as they are carefully instructed by a prescriber how the medication is to be taken. Shockingly, the maximum daily dose of over-the-counter painkillers is sometimes less tablets than the dose of prescription medications. Table 1 depicts the dosing and deaths from medications. Many of the prescription medications do not have data on deaths as they are rarely abused to a fatal level.

| Medication | Classification | Max Daily Dose | Tablets per Max Daily Dose | Deaths per Year |
|---------------|------------------|----------------|----------------------------|-----------------|
| Atorvastatin | Prescription | 80 mg | 8 | N/A |
| Amlodipine | Prescription | 10 mg | 4 | N/A |
| Lisinopril | Prescription | 40 mg | 8 | N/A |
| Esomeprazole | Over the Counter | 40 mg | 2 | N/A |
| Acetaminophen | Over the Counter | 4,000 mg | 12 | 500 |
| Ibuprofen | Over the Counter | 1,200 mg | 6 | 1000 |
| Naproxen | Over the Counter | 660 mg | 3 | 120 |

Table 1. Dosing of common medications and their classifications.⁶

Every year, over 56,000 patients visit the emergency room from acetaminophen alone. Of these emergency room visits, about 500 patients die from acetaminophen poisoning.⁸ Initially, there are no symptoms of the poisoning. However, after a day, liver function begins to go away, a patient's eyes become yellow, and the patient experiences a lack of energy. As shown in Figure 1, the deaths per year from acetaminophen poisoning have been on the rise in the United States. This is evidence that misuse of the medication is increasing every year.

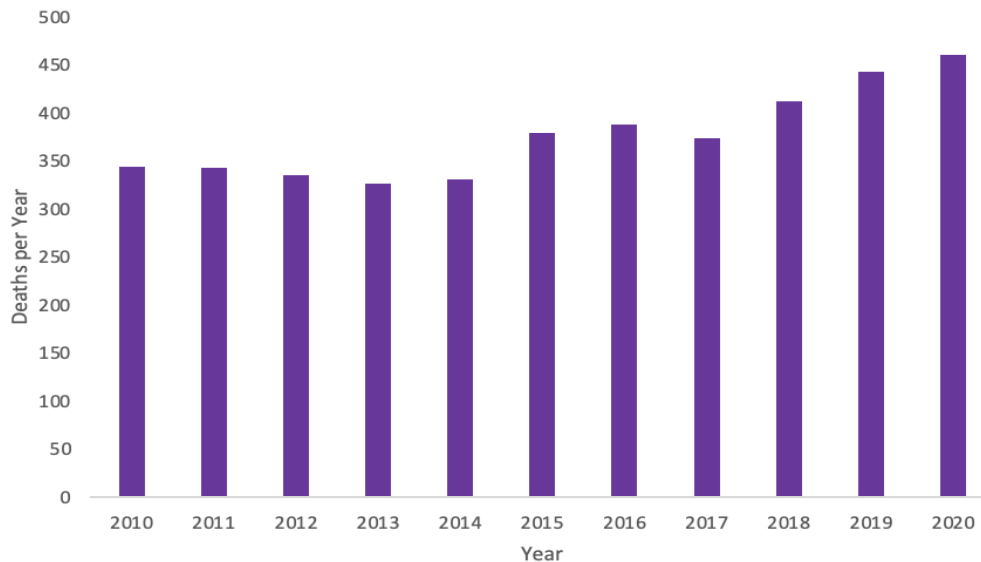


Figure 1. Deaths per year from acetaminophen in the United States⁹

Over-the-Counter Market

A leading reason for the prevalence of OTC abuse is the market value for these medications. As shown in Figure 2, the United States has spent over 85 billion dollars on over-the-counter medications. Initially, it may seem this is due to size and population. However, large countries such as China and India both had annual market values of only billion dollars. These medications are frequently used in the United States for daily pain. Large corporations want to push consumers to buy excess amounts of their product to continue making massive profits. If the growth continues, the United States will soon spend over 100 billion dollars on OTC medications, and abuse will continue to climb as well.⁸

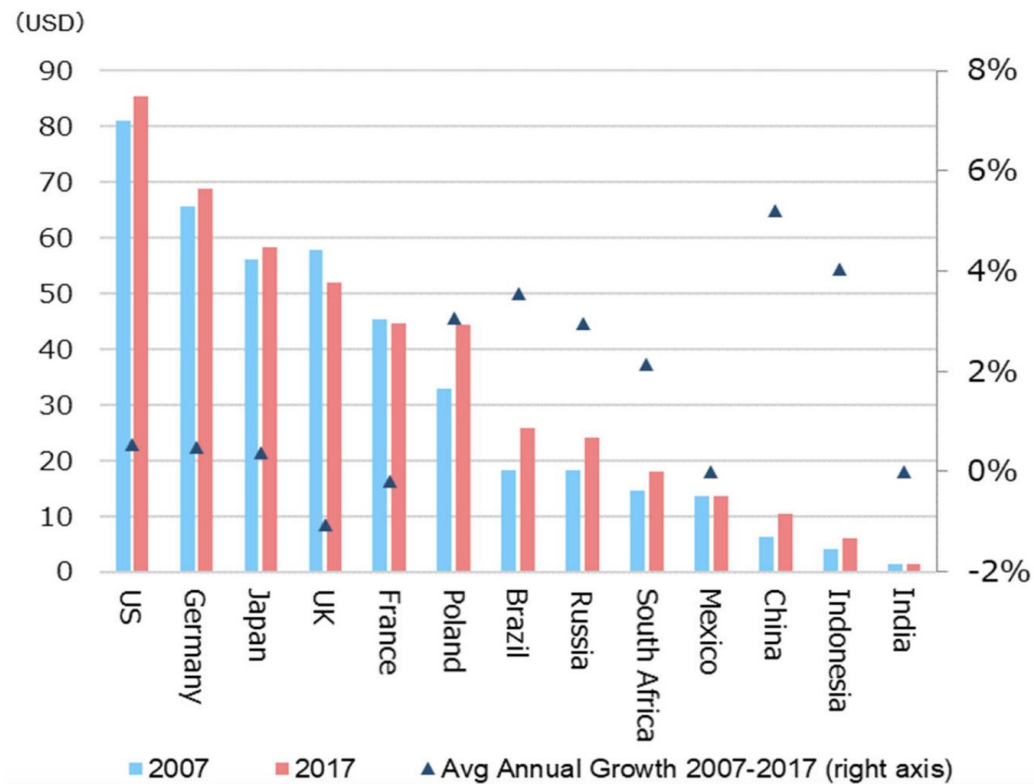


Figure 2. Amount spent on OTC medications in billions of USD.¹⁰

Real-Life Testimony

Often, the prevalence of medication abuse seems like a distant issue. It can seem like this is a topic that does not happen to people we know. However, this misuse of medication happens all over the country. In fact, it happens right here in our own city. During the research process, a patient who experienced the negative effects of unintentional painkiller abuse agreed to share her story. She asked to remain anonymous but was glad to have the opportunity to share her story and experience. She believes that her story will be able to serve as a warning and reminder to everyone

to use caution when taking painkillers and to follow the dosing advised by the medical professionals.

A few years ago, this patient was scheduled to have a double hip replacement. She had a successful surgery on one hip in 2019 and had her second surgery set for April 2020. Unfortunately, the COVID-19 pandemic changed everything, and her surgery was cancelled as it was not deemed necessary. To control the chronic pain she was feeling on a daily basis, she turned to over the counter painkillers. Initially, she began taking ibuprofen at the daily recommended dose. After a few weeks, she felt that the medication was not controlling the pain. She then increased the dose she was taking until the pain subsided. For several days, she took this high dose of ibuprofen as it was the only way she knew how to reduce her pain.

Over the course of a few more weeks, she began to feel lethargic and unmotivated. She had difficulty completing tasks and was not motivated to complete simple jobs around her house. During this time, she continued to consume high doses of ibuprofen every day. She notes that her quality of life was noticeable worse even though her hip pain was being moderately managed. Finally, after months had passed, she was able to reschedule her surgery. At this point, she was taking doses of

ibuprofen higher than a prescription dose. This was not being monitored by a medical professional, and her health was being affected.

The medical facility had the patient come in a few days before her surgery to have blood work done and assess overall wellness. The visit revealed shocking news. The patient was almost in complete renal failure. Her kidneys were functioning at only a fraction of the rate they should be. The doctors quickly deduced that the excessive intake of ibuprofen had damaged the kidneys over the past months. Instead of getting ready for surgery, the patient was monitored and treated for her kidney failure. The doctors said that patient that had she not been seen within the next week, she may have lost a kidney. Fortunately, they were able to treat her, and she made a full recovery in a short period of time.

There is a lot to learn from the patient's story. Firstly, it is an example showing that the misuse of over-the-counter medication happens in our own city, and it can happen to people who do not even realize it. Also, the story shows that the misuse of the medication can cause serious health problems, but mental and physical. The patient lost motivation and felt tired all the time. This took a toll on her mental health. Likewise, her kidneys were beginning to fail from the ibuprofen. She was under the illusion that the lack of energy was a result of her hip pain. It was coming from the medication she

was taking to alleviate the pain. She wanted to share her story to make others aware that this is a real issue. I am grateful to have learned from her how this can affect a person on a personal level.

Restrictions Around the Globe

In the United States, there are guidelines in place to attempt to limit the accidental abuse of over-the-counter painkillers. For example, the packaging on the pain killers has warning labels explaining the risk and effects of exceeding the daily dose of the medication. Additionally, the bottles containing the medication have child-resistance lids. This is done to prevent small children from consuming the medication. If a pharmacist dispenses these medications, they provide paperwork about the possible harms of the medication to the patient. However, abuse is still prevalent in the United States. These are steps in the right direction, but exploring policy in other countries provides intriguing solutions. ¹¹

Finland

In Finland, over-the-counter medications can only be purchased in the pharmacy. This restriction makes patients more mindful of how much of the medication they are consuming as there is only one place to buy it. Also, a pharmacist can see if a patient is excessively purchasing the medication and offer consultation. In the United States, the pain killers can be purchased nearly anywhere. Tylenol is available at

hotels, convenience stores, grocery stores, and even at some entertainment venues.

The widespread accessibility of the drugs without the supervision of a medical professional is a definite path to unintentional abuse.

United Kingdom

In some countries, there are restrictions on the quantity of over-the-counter painkillers that can be purchased at a time. For example, in the United Kingdom, a person can only purchase 32 tablets of acetaminophen from a pharmacy at a time. Also, the pharmacist provides a consultation for the patient and asks them questions to ensure they know the best safety practices. This reduces the amount of the medication a patient has, and therefore reduces the urge to take more than the recommended daily dose. Conversely, in the United States, acetaminophen can be purchased in large bottles of quantities of 1000 tablets from wholesalers such as Costco. It is much easier to obtain large quantities of the medication. This makes it easier to take an extra tablet here and there as patients have so much on hand. They will not run out of their supply quickly by taking a higher dose. The ability to buy these medications in large bulk quantities is another pathway to misuse.

Portugal

Some countries have also implemented age restrictions on over-the-counter medications. In Portugal, only patients over the age of 16 can purchase the over-the-

counter products. This is done to ensure that the patient is aware of the effects of the medicine. Additionally, all over the counter drug purchases are consulted by a pharmacist. The extra pharmacist to patient interaction is a great step to educate patients and address any concerns.

Next Steps

These restrictions have been successful in the respective countries. Of course, the changes may not be practical in the United States, but they do offer insight that changes can be made to limit misuse. A simple consultation with a pharmacist can clear up many questions. Instead of limiting the daily amount that can be bought, a pharmacy could offer consultations to anybody buying a large quantity. This protects all parties and ensures safety.

Conclusion

Over the counter painkillers are incredible medications. They are an irreplaceable medical tool for stopping pain, fever, inflammation, and discomfort from daily life. Unfortunately, abuse and misuse of these medications is prevalent in the United States. Over 56,000 emergency visits from acetaminophen and over 400 deaths a year from acetaminophen alone are just one statistic confirming the abuse. The easy of obtaining these medications in bulk quantities is a driving factor for misuse. The market for the medications is disproportionately larger in the United States than any

other county. There are hardly any restrictions regarding the purchase of the medications. The more these drugs are purchased without proper information and guidance, the more deaths we will see.

To stop the clear abuse of the medication, we can turn to other countries for guidance. Limiting purchase quantities, restricting purchasing locations, and requiring consultation with a pharmacist are all valid techniques to limit abuse. When less of the medication is at home, it is much easier to not take an excessive dose.

Abuse of medication will never fully go away. However, by informing the public of the dangers of misuse of medications, sharing real-life testimony, and attacking the issue with a full head of steam, a change can be made. A reduction in the deaths and hospitalizations will be made, and we will still be able to manage our pain with the proper use of medication.

References

- (1) Blantz, R. C. Acetaminophen: Acute and Chronic Effects on Renal Function. *American Journal of Kidney Diseases* **1996**, 28 (1, Supplement 1), S3–S6.
[https://doi.org/10.1016/S0272-6386\(96\)90561-2](https://doi.org/10.1016/S0272-6386(96)90561-2).
- (2) Agrawal, S.; Khazaeni, B. Acetaminophen Toxicity. *StatPearls* **2023**.
- (3) OTC Drugs Becoming More Like Consumer Goods —Business Opportunities Extending to Other Industry Players—. **2019**.
- (4) Oleszkiewicz, P.; Krysinski, J.; Religioni, U.; Merks, P. Access to Medicines via Non-Pharmacy Outlets in European Countries—A Review of Regulations and the Influence on the Self-Medication Phenomenon. *Healthcare (Basel)* **2021**, 9 (2), 123. <https://doi.org/10.3390/healthcare9020123>.
- (5) Cooper, R. J. 'I Can't Be an Addict. I Am.' Over-the-Counter Medicine Abuse: A Qualitative Study. *BMJ Open* **2013**, 3 (6), e002913.
<https://doi.org/10.1136/bmjopen-2013-002913>.
- (6) Budnitz, D. S.; Lovegrove, M. C.; Crosby, A. E. Emergency Department Visits for Overdoses of Acetaminophen-Containing Products. *American Journal of Preventive Medicine* **2011**, 40 (6), 585–592.
<https://doi.org/10.1016/j.amepre.2011.02.026>.

- (7) Ibuprofen/Codeine Abuse. *React. Wkly.* **2010**, 1322 (1), 17–17.
<https://doi.org/10.2165/00128415-201013220-00053>.
- (8) Myers, R. P.; Shaheen, A. A. M.; Li, B.; Dean, S.; Quan, H. Impact of Liver Disease, Alcohol Abuse, and Unintentional Ingestions on the Outcomes of Acetaminophen Overdose. *Clinical Gastroenterology and Hepatology* **2008**, 6 (8), 918–925. <https://doi.org/10.1016/j.cgh.2008.02.053>.
- (9) Hughes, G. F.; McElnay, J. C.; Hughes, C. M.; McKenna, P. Abuse/Misuse of Non-prescription Drugs. *Pharm World Sci* **1999**, 21 (6), 251–255.
<https://doi.org/10.1023/A:1008788726842>.
- (10) Conca, A. J.; Worthen, D. R. Nonprescription Drug Abuse. *Journal of Pharmacy Practice* **2012**, 25 (1), 13–21. <https://doi.org/10.1177/0897190011431148>.
- (11) Wazaify, M.; Shields, E.; Hughes, C. M.; McElnay, J. C. Societal Perspectives on Over-the-Counter (OTC) Medicines. *Family Practice* **2005**, 22 (2), 170–176.
<https://doi.org/10.1093/fampra/cmh723>.