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Gap Analysis of Pharmaceutical and Personal Care Product (PPCP) Disposal and an Indicator of Consumer Awareness

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GAP ANALYSIS OF PHARMACEUTICAL AND PERSONAL CARE PRODUCT (PPCP) DISPOSAL AS AN INDICATOR OF CONSUMER AWARENESS

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GAP ANALYSIS OF PHARMACEUTICAL AND PERSONAL CARE PRODUCT (PPCP) DISPOSAL AS AN INDICATOR OF CONSUMER AWARENESS

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by

Melissa C. Seguin

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DEDICATION

I dedicate this thesis to my husband and daughters. Their constant love, patience, and support of my never-ending quest for more knowledge have nourished this work from its slow birth to its fully matured status. I am forever grateful for their unwavering and unconditional love throughout this journey.

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ABSTRACT OF THE THESIS

GAP ANALYSIS OF PPCP DISPOSAL AND CONSUMER AWARENESS

by

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American Public University System, May 10, 2015

Charles Town, West Virginia

Professor Elizabeth D'Andrea, Thesis Professor

This study addresses the growing problems posed by PPCP disposal and the resulting challenges faced by consumers, water treatment experts, environmentalists, and scientists. While other studies have addressed some of these challenges, this study investigates the true root cause of incorrect disposal practices, concentrating on prevention rather than on symptoms of this issue. This study examines current literature on the manufacturing, packaging, and marketing of PPCPs to help identify potential gaps that contribute to poor disposal practices and ultimately introduce risks to humans and the environment. Finally, available studies, product information and other literature are examined using a content analysis to code for key concepts and ideas. Using the information gathered, a root cause analysis indicates gaps in consumer PPCP disposal practices are a direct result of limited consumer knowledge. Additionally, manufacturer-provided product information and advertising were key factors influencing levels of consumer awareness.

Consequently, consumers were uninformed on the human and environmental threats posed by incorrectly disposing of PPCPs.

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I. INTRODUCTION

"In vain have you acquired knowledge if you have not imparted it to others."

- Deuteronomy Rabbah

In today's society, purported remedies exist for just about any malady, ailment, or other complaint one can imagine. A variety of prescription and over-the-counter (OTC) creams, gels, pills, and liquid medications offer instant relief and cures for some of the population's most common medical complaints and diseases. An array of cosmetics and other beauty aids also constantly tempt us with promises of thinner waistlines, shinier hair, less wrinkles, increased energy, and whiter teeth. Advertisements for these items which are categorized in general as pharmaceuticals and personal care products (PPCPs) flood mainstream media sources, taking up prominent space in magazines and airing on television during prime viewing hours.

Between 1990 and 2000, the United States (US) spent approximately $2.5 billion on advertising for prescription and OTC products (Mintzes, Barer, Kravitz, Kazanjian, Bassett, Lexchin, ... & Marion, 2002), and grew to over $200 billion by 2007 (Glassmeyer, Hinchey, Boehme, Daughton, Ruhoy, Conerly, ... & Thompson, 2009), accounting for an eighty percent increase in sales over a seven year period. These products are available to consumers through direct purchase in stores or on the internet, prescription, or via free samples offered in many doctor's offices. Some health and beauty aid samples are sent to customers using online marketing tools that involve the shipping of four to five new products each month in exchange for specific consumer feedback. However, these items and other PPCPs, when unwanted, unused or expired, accumulate over time and tend to clutter and crowd our medicine cabinets and toiletry bags, or worse, end up being disposed of in a manner that could harm humans, animals, and the environment.

Barrett (2005) indicates that many companies safeguard their product formulations leaving the consumer with insufficient knowledge to make proper decisions on use and disposal. Many of the labels on these products warn against use if one has certain medical conditions or is using other medications that could interfere with the products intended benefits. Some labels also recommend contacting a Poison Control Center in the event of overdoses. However, PPCP packaging typically only provides the consumer with information about suggested medication dosages, potential side effects and contraindications for use, and fails to address basic disposal recommendations. Many prescription and OTC medication labels direct consumers to take the product as needed to produce a desired effect or to relieve certain symptoms. Yet, if any of the medications are unused or fails to satisfy the needs of the consumer, many of these end users are left with excess or expired medications and do not know how to properly dispose of them. Medicine cabinets across the country harbor at least one or more of these types of products and indicate a growing problem surrounding their ultimate fate. This lack of consumer information on proper procedures to follow to correctly dispose of PPCPs increases the risks of contamination to soil and water resources.

If the environment could file a wrongful death or injury lawsuit against consumers who have thoughtlessly disposed of their unused medications and other health care products in the sink, toilet, or in regular household trash, many would be unable to escape accountability for their actions. However, sole responsibility for proper disposal decisions does not lie with the consumer alone. If the average consumer does not know or understand the dangers or the implications of improper PPCP disposal, manufacturers of these products must also share in the responsibility for ensuring PPCPs are disposed of correctly so that society can do their part in safeguarding our human and environmental resources. Some research into the ethical framework

of our society suggests that without regulatory or coercive action, most of the public will continue to overuse and overburden common-use resources such as land and water without a thought given to the notion that these are not expendable or renewable resources (Hardin, 1986/2012, p. 272). Existing stores of fresh water and uncontaminated soil continue to be adulterated through incorrect disposal of PPCPs and other harmful pollutants and will eventually be unable to recover.

The purpose of this research is to identify gaps that currently exist in disposal methods for unwanted, excess, and expired PPCPs throughout the United States (US). Currently, a standardized or regulated method for turn-in and disposal of PPCPs does not exist within the US. Disposal methods vary between states and among PPCP manufacturers leaving the majority of the population confused and unsure of the correct process to follow to discard their unused or out-of-date PPCPs. To exacerbate the issue, many people do not even understand why it is important to divert excess or unused PPCPs away from sanitary sewers and landfills. Mounting evidence indicates an increased presence of contaminants of emerging concern (CECs) in soil and water, some of which originates from incorrect disposal practices.

The United States Department of Justice (DOJ), Drug Enforcement Administration, Office of Diversion Control (2015), proactively hosts periodic drug take-back initiatives in most major, metropolitan areas but many of these events lack proper advertisement and do not reach those in more rural areas. This issue is a matter of growing concern across the US as drug manufacturers introduce new medication formulations and cosmetic industry promoters launch new product lines every day, posing an ever changing array of threats to land and water resources. Ultimately, it does not matter whether these products are excreted from the body into home septic systems and sewage treatment facilities or thrown into landfills; both avenues

eventually lead back to water resources (Kotchen, Kallaos, Wheeler, Wong, & Zahller, 2009, p.1476). Additionally, advanced water treatment technologies are very costly, consumer awareness is not as good as it could be, and there is a lack of standardization surrounding consumer disposal of PPCPs.

A lack of knowledge on proper procedures for correctly disposing of excess or expired pharmaceuticals and personal care products leads to potential contamination of soil and natural water resources. Manufacturers of PPCPs focus on increasing profit margins for their companies, avoiding direct human and ecological risks, and delivering as much of their product to the consumer as possible. However, indirect consequences begin to surface as these products expire or consumers deem them as excess. Major drug and cosmetic companies have previously overlooked this particular aspect of their product's life cycle. The concept of cradle-to- grave management of potentially hazardous waste was first introduced by the United States Environmental Protection Agency (USEPA) (2012) to ensure sound stewardship in the creation, use, and disposal of potentially hazardous products. This concept later evolved into a cradle-to-cradle approach to address the issue of sustainability. The potential for environmental benefit exists for manufacturers of PPCPs who consider adopting a similar approach.

Clear identification of the current gaps in PPCP disposal across the US will allow for more focused mitigation actions in the future. While many consumers, especially those in areas that are more metropolitan, understand how to dispose of excess or expired PPCPs, there is still a large sector of the population, especially in rural areas, that is unaware of proper disposal methods. Moreover, unfortunately, many people still falsely assume they can simply flush or pour their unused PPCPs down the drain or toss them in with normal household wastes.

Therefore, it is imperative to explore and document the current gaps in disposal processes, suggest ways to better regulate and increase public awareness, and ultimately reduce the burden on our environment.

This study evaluates the connection between gaps in education and information on proper disposal and turn-in of excess or expired PPCPs and the level of consumer awareness. The study reviews various methods used to disseminate product disposal information to the end-user, examines the existence of specific environmental warnings or risks on product labeling or on package inserts aimed at educating the consumer, and determines whether manufacturers provide alternate methods for discarding excess or expired products. An additional aspect evaluated in this study focuses on drug take-back or turn-in events, specifically whether they are well advertised, user-friendly, and organized in a manner that will reach all levels within a community, regardless of its socioeconomic composition.

II. LITERATURE REVIEW

This study begins with an overview of consumer PPCP disposal and then progresses into a review of available literature on the proper handling and disposal of PPCPs obtainable through manufacturer guidance on package labels, product inserts, and in advertisements. A review of this information will indicate the level of manufacturer involvement in product life cycle outcomes and provide insight into the environmental ethic embodied by companies that manufacture PPCPs. The study then continues by examining existing scholarly scientific research and studies on environmental threats posed by improper disposal of PPCPs. Many of the studies have prompted government officials to implement new limits on the presence of certain pharmaceuticals in drinking water and wastewater, necessitating the incorporation of

more sophisticated monitoring and removal equipment and processes at municipal water treatment facilities throughout the US. Finally, the study concludes with a review of pertinent federal regulations as well as existing PPCP disposal programs and incentives aimed at increasing consumer participation and preventing adverse impacts on humans and the environment.

The literature review will ultimately reveal several critical gaps in consumer education and information pertaining to correct procedures and methods to utilize for proper PPCP disposal. The study will also highlight the importance of educating consumers on the increased potential for negative effects on society and our natural resources resulting from poor consumer disposal practices and the positive impacts achievable by practicing proper PPCP on disposal habits. In addition, the study will emphasize the importance of consumer participation in voluntary take-back events.

An Overview of Consumer PPCP Disposal

In today's commercial and private communities, patrons widely accept and practice the concept of reducing, reusing, and recycling as a means to minimize waste, protect the environment, and support sustainability. With increased environmental awareness and acceptance of the premise that many of the planet's natural resources are finite and not renewable, it is becoming more important than ever to properly dispose of wastes to prevent any added burden on these resources. While reduction, reuse, and recycling efforts play a significant role in reducing these threats, minimal guidance has surfaced on the proper management of expired or excess PPCPs, especially for consumers. Disposal of these types of products can be reduced through other means; however, reuse and recycling is forbidden, especially for

prescription medications that are categorized as controlled substances. Disposal for this category of PPCPs requires the presence of law enforcement (Ruhoy & Daughton, 2008, p. 1162). However, most consumers do not know this information and continue to dispose of their unwanted PPCPs in ways that are convenient for them, regardless of the potential impacts on humans and the environment.

Consumers normally dispose of their excess or expired PPCPs in the sanitary sewer, mostly by flushing down the toilet or pouring liquids down the sink drain. In addition, most assume these practices are still acceptable because they have not received information or education telling them otherwise. Although the USEPA and the United States Food and Drug Administration (USFDA) have both published updated guidance on proper disposal of expired or excess medicines, much of this new information does not reach the average consumer. PPCP packaging does not contain this updated information, nor does current advertisements for these products. Obvious gaps between what is known about proper PPCP disposal practices and what is shared with the consumer begin to emerge and are predictive of the current levels of consumer awareness and consequently, the continued threat to the environment.

Definition of Terms

The following terms are defined for clarity and consistency:

'Contaminants of Emerging Concern' or CECs are chemicals that have previously "not been detected or are being detected at levels that may be significantly different than expected" (USEPA, 2014). Many of these CECs have been around for a long time and have only recently become a concern because of enhanced analytical processes that allow for more definitive quantification and detection (Sanderson & Solomon, 2009, p. 1359).

'Pharmaceuticals and personal care products' or PPCPs comprise a category of CECs that include health and beauty products, and prescription and non-prescription medications intended for both human and animal use, and nutritional-based supplements (USEPA, 2012). For the purposes of this study, pharmaceuticals will refer to physician-prescribed products for humans and animals, over-the counter medicines, and dietary supplements; and personal care products will refer to health and beauty items such as hair care products, sunscreens, lipsticks and other cosmetics, body soaps, lotions, and perfumes (Kreisberg, 2007, p. 50). However, cosmetics in particular are separated into 'chemical groupings' for health and safety testing with their risks being evaluated in these groupings versus individually (Nohynek, Antignac, Re, & Toutain, 2010, p. 253).

'Over-the-counter' or OTC medications refer to a category of products one may purchase without a physician's approval. For the intent of this study, OTC products refer to items intended for use by humans or animals, and include tablets, capsules, liquids, ointments, lotions, gels, soaps, shampoos, and creams.

'Active pharmaceutical ingredient' or API is the component of any PPCP, either prescription or OTC, which is added to produce or prevent a given effect and is regulated by the USFDA. Some APIs are more persistent than others within the environment, with many being completely metabolized by the body while others are only partially metabolized then excreted through feces and urine into the sanitary sewer. In this study, disposal of APIs refers to any direct or indirect method used other than through regulated waste disposal processes.

'Endocrine disrupting chemicals' or EDCs are found in a variety of PPCPs, foods, and insect repellents and are suspected to disrupt normal male and female reproductive cycles, the immune system, and neurological function in humans and non-human populations (World Health

Organization, 2015). As referenced in this study, EDCs represent some of the more serious threats posed by improper disposal of PPCPs.

Product Labeling

Product labeling requirements have greatly evolved over the years. However, insufficient medication labeling is still touted as the leading cause of drug errors (Shrank, Agnew-Blais, Choudhry, Wolf, Kesselheim, Avorn, & Shekelle, 2007). With little to no regulation to govern the labeling of early forms of PPCPs, minimal information was placed on containers and inconsistencies were rampant. Some bottle labels were more elaborate than others were, with some containing almost no information at all. In addition, at that particular time in history, consumers enjoyed a much more robust relationship with their physician as most were imbedded in the communities where they worked and lived. Consumers relied heavily upon their physician to provide them with dosing information and typically, only small amounts of medicines were prescribed because of limited access and availability of medicinal products. This prevented the need for disposal but still posed a potential threat to human health and the environment because early sewer systems were grossly ineffective. In addition, early apothecaries used a variety of containers for these products, ranging from bottles, jars, and vials to sacks and boxes, with each having varying types of labels that were valued more for their decorative nature versus informational content (USFDA, 2013). In the event of an accidental spill or an overdose, this lack of product identification posed additional threats to consumers and natural resources.

By the mid 1800's, amid escalating concerns over drug safety and quality and a growing reliance on imported drugs, the US took decisive action to introduce some form of regulation to the pharmaceutical industry (USFDA, 2013). In an effort to regulate product content and

labeling, the US passed the Pure Food and Drugs Act in 1906 and later provided updated guidance in the Food, Drug, and Cosmetic Act of 1938 (USFDA, 2013). These regulations marked the beginning of many labeling changes in both the food and drug industries. However, with increasing pressure to minimize packaging sizes and simultaneously add more information to the labels, manufacturers began to seek other methods to include the required minimal information on their products.

The requirements for OTC product labeling are outlined in Title 21, Subpart C, Section 201.66(c)(2) and (d) of the US Code of Federal Regulations (CFR), i.e., 21CFR 201.66(c)(2) and (d). Figure 1 illustrates the mandatory information required on OTC product labels and the order in which they should appear. Labels must include the following:

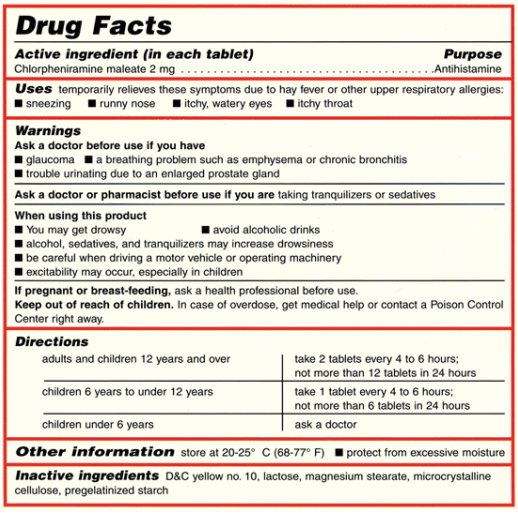
- A list of the APIs contained in each dose
- The product's function or purpose (e.g., decongestant or antihistamine)
- A description of what the product should be used for (i.e., symptoms)
- Warnings such as when the product should and should not be used, when you should seek guidance from your pharmacist or physician, descriptions of potential side effects, and activities or substances that should be avoided
- Instructions on when to take the medication, how much to take, and frequency at which to take each dose, e.g., three times per day
- And a list of ingredients in the product that are inactive for the purpose of identifying ingredients capable of producing allergic reactions (USFDA, 2009).

The requirements for cosmetic and personal care product labeling are outlined in 21 CFR 701.3(d). Figure 2 illustrates this information. These types of products must include the following information on their main label and information panels:

- Main Label
    - Product identification
    - Net quantity or weight of product
- Information Panel
    - Name and address of business
    - Statement by distributor with specific wording to indicate whether the aforementioned name and business address is that of the manufacturer or distributor
    - Facts about the product such as specific instructions for safe usage
    - Cautionary or warning statements (e.g., flammable products such as hair spray)
    - List of product ingredients in "descending order of predominance" (USFDA, 2014)

The labeling requirements for prescription medications are much more detailed and are outlined in approximately two dozen federal guidance documents for drugs ranging from opioids and acne products to estrogen and oral contraceptives, with specialized information provided specifically for geriatric and pediatric patients (USFDA, 2015). However, in a separate study on the readability and comprehensibility of OTC product labeling, researchers found that some consumers had difficulty understanding the information provided on product labels while others expressed a satisfactory response in comprehending the labels (Tong, Raynor, & Aslani, 2014, p. 865). Most notable in the original and subsequent labeling guidance provided by the federal government and PPCP manufacturers is the absence of specialized handling and disposal instructions for consumers, pointing to potential industry-wide gaps in information sharing.

However, other gaps exist that could also be significant contributors to the root cause of PPCP disposal issues.



Drug Facts

Active ingredient (in each tablet) — **Purpose**
Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Figure 1. OTC Drug Label Requirements (Source: USFDA, 2009)

Figure 2. FDA-Approved Cosmetic Label (Source:www.soapqueen.com)

Patient Package Inserts

PPCP labels are not the only source of confusing and sometimes incomprehensible information provided to consumers. Patient package inserts, also referred to as PPIs, offer an additional source of data that may even frighten some patients as suggested by a group of researchers studying patients' emotional responses after reading a selected set of prescription package inserts (Herber, Gies, Schwappach, Thürmann, & Wilm, 2014). These information inserts or leaflets provide a variety of information to both medical providers and patients on risks associated with product use in an "easy-to-read format" (USFDA, 2009). However, the average length of PPIs for the prescription drugs reviewed during this study was approximately 18 pages with length being dependent on print font size. According to Herber, Gies, Schwappach, Thürmann, & Wilm (2014), even recent improvement efforts targeted at making PPIs easier to

read and understand have fallen short of their goal and continue to leave patients confused and ill prepared to make informed choices about their treatment regimens (p. 2).

Compounding readability issues, one focus group of patients reported they felt ill simply from reading the lengthy and unusually small text in the PPIs (Herber, Gies, Schwappach, Thürmann, & Wilm, 2014, p. 4). As a result, several of the patients admitted to some of the following negative behaviors: not reading the insert, only skimming its contents, throwing the insert in the trash, looking to other sources for needed information, discontinuing medication usage, or changing their dosage without seeking guidance from their physician (Herber, Gies, Schwappach, Thürmann, & Wilm, 2014, p. 4). The most common behaviors exhibited were looking to other sources for needed information, and discontinuing medication usage, consequently increasing the potential for receiving misinformation and for accumulation of unused medications (Herber, Gies, Schwappach, Thürmann, & Wilm, 2014, p. 4). Moreover, patients from the focus group reported a general inability to understand the medical terminology used in the PPIs, claiming that the level of language used is too high for the average consumer (Herber, Gies, Schwappach, Thürmann, & Wilm, 2014, p. 5).

The USFDA (2015) recommends manufacturers use simple language that is easily understandable and preferably written in a 10-point font size, and between a 6^{th} to 8^{th} grade reading comprehension level. However, since this is only a recommendation, no standardization currently exists in the development and printing of PPIs, creating drastic inconsistencies in information provided by PPCP manufacturers to the end users of their products. As Herber, Gies, Schwappach, Thürmann, & Wilm, (2014) point out in their study on triggered behaviors associated with PPIs, patients rely heavily on their medical providers for a variety of information