Over-the-Counter and Out-of-Control: Legal Strategies to Protect Youths From Abusing Products for Weight Control

Jennifer L. Pomeranz, JD, MPH, Lisa M. Taylor, JD, S. Bryn Austin, ScD

Abuse of widely available, over-the-counter drugs and supplements such as laxatives and diet pills for weight control by youths is well documented in the epidemiological literature. Many such products are not medically recommended for healthy weight control or are especially susceptible to abuse, and their misuse can result in serious health consequences.

We analyzed the government's role in regulating these products to protect public health. We examined federal and state regulatory authority, and referred to international examples to inform our analysis. Several legal interventions are indicated to protect youths, including increased warnings and restrictions on access through behind-the-counter placement or age verification.

We suggest future directions for governments internationally to address this pervasive public health problem. (*Am J Public Health*. Published online ahead of print December 13, 2012: e1–e6. doi:10.2105/AJPH.2012.300962)

ABUSE OF WIDELY AVAILABLE, over-the-counter (OTC) drugs and supplements such as laxatives and diet pills by adolescents and adults for weight control is well documented as a national problem in the United States in the epidemiological literature.[1,2] Many of these products are not medically recommended for healthy weight control or are ineffective for weight loss, even in the short term.[1,3–5] Abuse of these products affects both males and females of all racial, ethnic, and socioeconomic groups.[1,6] The National Comorbidity Survey Replication, a nationally representative study of US households, found that 50% of people with bulimia nervosa, a disorder often associated with abuse of laxatives and diet pills, develop the illness by age 18 years.[7] Among US adolescents, 6% of girls and 4% of boys reported past-month use of diet products without physician advice.[2] Serious health consequences can result from abuse of these OTC products, such as acute and chronic impairment of gastrointestinal and cardiovascular systems, sometimes resulting in death.[8] Adverse effects include dehydration, chronic diarrhea and constipation, metabolic acidosis, hypokalemia, and other fluid and electrolyte disorders; cardiac arrhythmia; hemorrhagic and ischemic stroke; and hepatic and renal failure.[3,4,9–12]

Products and product categories that have been widely abused for weight control include those explicitly marketed for such purposes, but also other products only believed to aid in weight control, including laxatives and syrup of ipecac.[9,13,14] OTC laxatives are medically approved to treat constipation, but have received a fair amount of attention in the epidemiological and medical literatures because of their prevalence of abuse. Based on their review of more than 70 studies, Neims et al. estimated the lifetime prevalence of laxative abuse for weight control to be 4% of the general US population, affecting many millions of Americans.[15] Estimates of the lifetime prevalence of laxative abuse from studies of patients diagnosed with bulimia nervosa or eating disorders not otherwise specified have ranged from 15% to as much as 62%.[16] In a large, community-based sample of adolescents, past-year use of laxatives for weight control purposes was estimated to be 2% in girls and 1% in boys.[6]

In 2007, the US Food and Drug Administration (FDA) approved the first nonprescription diet drug, orlistat, for OTC status. Orlistat is a weight-loss drug that prevents the absorption of fat from food and has a laxative-like effect.[17] Prescription strength orlistat was approved at 120 milligrams in 1999 for obesity management, and in 2007, the FDA approved orlistat 60 milligrams for OTC status under the name alli. Concerns about potential misuse and abuse of orlistat were raised by eating disorder experts upon its OTC approval[18] and continue to be raised globally as the drug becomes more accessible internationally.[19] Studies are emerging to support these concerns. A study with a clinical sample of patients with eating disorders found that 6% misused alli, most often in an effort to compensate for a binge eating episode.[20]

Despite the ineffectiveness and potential harm of many products used and misused for weight control, the global market for diet management and weight loss products was estimated to be $363 billion in 2009 and is projected to reach $586 billion by 2014.[21] In addition, the sale of products not overtly marketed for weight loss but abused for weight control generates millions of dollars each year. In 2008, total sales of OTC laxatives in the US approached $290 million.[22] It is significant that OTC laxatives are substantially less expensive than alli, and thousands of pills can be purchased for a fraction of the price of alli.[23,24] Both drug products are widely available in retail establishments, pharmacies, and on the Internet, and both are advertised directly to consumers, with the manufacturer of alli employing a celebrity spokesperson in its advertisements.[25]

In light of the epidemiological evidence documenting the abuse of OTC laxatives and the increasing concerns over potential misuse of alli, we obtained a pilot grant to examine current US regulations pertinent to these 2 OTC drug products. We analyzed the US government's legal authority to increase regulation to address outstanding public health concerns. Available legal methods include requiring warning labels and regulating permissible locations

where such products may be sold. We thus analyzed federal and state regulatory authority and looked to specific international examples of countries with known regulation of diet products to inform our analysis and provide context for the consideration of alternative restrictions. We have set forth this research and provided recommendations for increased regulations.

REGULATORY AUTHORITY

The FDA has regulatory authority over the safety, efficacy, and labeling of prescription and nonprescription drugs. In 1951, the US Congress codified the distinction between prescription and OTC drugs. A prescription drug is so designated

> because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.[26]

This distinction is intended to both protect the public and relieve pharmacists and the public from burdensome restrictions on dispensing drugs that are generally recognized as safe.[27] The box on this page defines dispensation terms.

The FDA has the authority to designate a drug as OTC or prescription but more frequently, OTC drug manufacturers can legally market drugs without preapproval as long as they comply with the previously established OTC drug monograph, which typically lists acceptable ingredients and required labeling information.[28] The FDA, therefore, does not review each OTC drug product or label but it does require a specific format and content for OTC labels, including listing ingredients, explanations of proper use, and warnings against unsafe use, side effects and adverse reactions.[29] Because no drug is absolutely risk-free, labels are intended to address outstanding concerns of harm, toxicity and conditions of safe use to allow for OTC status.[30,31]

Beyond basic instructions, the FDA often establishes specific warnings for products that may cause harm under proper use, such as potential allergic reactions or organ damage.[32] The FDA also has the regulatory authority to require warnings for a product when "foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings."[33] For example, reports in the medical literature and data accumulated by the FDA indicated that consumers were confused about proper dosing of sodium phosphate laxatives, resulting in death, so the FDA required a warning stating that, "Taking more than the recommended dose in 24 hours can be harmful."[34] Therefore, if misuse becomes reasonably foreseeable, increased factual warnings are considered necessary to protect consumers.[33]

Government regulations that require the disclosure of factual information are consistent with the First Amendment of the US Constitution.[35] Industry challenges to disclosure requirements are generally only successful when the government has sought to require subjective information be placed on the product packaging.[36] Requiring purely factual disclosures, warnings, and disclaimers have been upheld as a valid use of government authority to protect and inform consumers.[37]

The Federal Trade Commission is responsible for regulating the advertisement of OTC drug products. Advertisements for OTC drugs must be truthful and nondeceptive and manufactures must have a "reasonable basis" for any claim they make.[38] If a claim relates to health, safety, or product efficacy, it must additionally meet the standard of "competent and reliable scientific evidence."[39] This means that tests, studies, and research must be objectively conducted, based on accurate and reliable procedures, and evaluated by qualified people.[39] The Federal Trade Commission additionally supports a set of voluntary guidelines for marketers of weight-loss products that encourages the disclosure of weight-loss related information and product-specific risks.[40]

In general in the United States, prescription drugs are administered by a pharmacist and OTC drugs can be sold in any retail establishment on open shelves. The designation of specific drugs as being available behind-the-counter (BTC) is a recent introduction to the US market. The FDA and Congress have not codified this "third class" of drugs to create an official designation, but the federal government has permitted or required certain drugs to be sold BTC for reasons directly relevant to the specific drug, the approved user, and public health considerations.[41] For example, the FDA granted the emergency contraceptive, Plan B, nonprescription BTC pharmacy-only status for women older than 18 years in 2006.[41] (The drug remains prescription-only for those younger than 18 years.) In a similar vein, Congress enacted a law requiring cold medicines containing pseudoephedrine to be located BTC because of concerns over its use in illicit drug-making.[42] The law limits the amount an individual may purchase within a 30-day

Definitions of Terms Relating to Drug Dispensation

Term	Definition
BTC	Behind the counter of any retail establishment (no pharmacist required to be on the premises)
BTC pharmacy	Behind the counter of pharmacies only (requiring contact with pharmacy staff)
OTC	Over-the-counter of any retail establishment (not requiring prescription or contact with pharmacy staff)
OTC pharmacy	Over-the-counter in pharmacies only but not requiring contact with a pharmacist
Prescription	Requires physician prescription (only available in pharmacies and requiring contact with pharmacy staff to obtain drug)
Retail establishment	Place that sells over-the-counter products
Pharmacy	Place that sells over-the-counter products and prescription-only products; also called drug stores

period and requires photo identification for purchase.[43]

Considerations relevant to altering the drug classification system in the US, such as increased costs or increased need for pharmacists,[44] are outside the scope of this article because the current analysis is limited to only 2 drugs. However, it is noteworthy that the American Pharmacists Association released a statement supporting the development of a regulatory process for a third class of BTC drugs.[45] Furthermore, unlike the United States, other countries have multiple drug classifications. The US General Accounting Office conducted a study of nonprescription drug practices of select countries and found that they include prescription, BTC pharmacy, BTC, OTC pharmacy, OTC, and OTC but a pharmacist must be present for consumer consultation.[44] For example, the United Kingdom follows a 3-tier drug classification system (prescription, BTC pharmacy-only, and OTC) that has been in place since 1995. The European Union has a centralized approval process but leaves to each member state the decision to designate the location of approved products among the various classifications.[44] Conversely, in Australia each state and territory has the authority to determine drug classification independently, but they have all adopted the national scheduling orders, which include 4 classifications: prescription, BTC pharmacy, OTC pharmacy, and OTC.[44]

In the United States, states and local governments (collectively states) cannot enact laws that conflict with federal law.[46] In the context of OTC products, this prohibition includes warning and labeling requirements on packaging and shelf signs that are not identical to those required by the FDA.[47] However, states can regulate the practice of pharmacies,[47] and this includes the ability to regulate the location of products, such as requiring OTC drugs to be located BTC. For example, New York recently passed a law requiring that ipecac be located BTC.[48] Similarly, prior to the federal act, several states enacted laws requiring that pseudoephedrine-containing products be placed BTC and several retailers voluntarily did the same.[49] Now, 2 states have enacted, and many states are considering, laws that require prescriptions to obtain pseudoephedrine-containing drug products.[50]

CURRENT REGULATIONS FOR OVER-THE-COUNTER LAXATIVES

The FDA established a drug monograph for OTC laxatives.[51] Manufacturers may produce products with the approved ingredients and must provide appropriate instructions for use, including daily dosing.[51] Except for FDA action on sodium phosphates, there has been relatively little regulation of OTC laxatives and no required warnings associated with their misuse. Perhaps because laxatives have been medically utilized for centuries,[16] little restriction has been placed on their sale.

Only 1 US state has a restriction related to dispensing laxatives and this is based on reports of laxative abuse among individuals engaged in sports with weight requirements.[16] In California it is a misdemeanor for a coach to give laxatives to a minor for nonmedical purpose, such as to lose weight related to participation in a sport.[52]

Internationally, there is also little regulation on OTC laxatives. A common OTC laxative ingredient, bisacodyl, is OTC in Australia and the United Kingdom, but is OTC pharmacy in Italy and the Netherlands.[44] Bisacodyl is also available for purchase online in 1000 pill count bottles for little cost.[53]

RECOMMENDED REGULATIONS FOR OVER-THE-COUNTER LAXATIVES

OTC laxatives are medically indicated only to relieve constipation but are misused by many as a misperceived method of weight control. Epidemiological research confirms that a substantial portion of patients with eating disorders and other people seeking weight control abuse laxatives. Research also indicates that young people start abusing laxatives without knowledge of the enormous health risks. Because it is established from research that abuse and misuse is reasonably foreseeable, the FDA should consider requiring warning labels on these products.

The lack of adequate instructions and warnings makes a product dangerous in light of the foreseeable risks of harm posed by the product.[33] The FDA should consider amending the OTC laxative drug monograph to include several requirements. First, the instructions on use should not only recommend daily dosage but should also indicate an appropriate duration of administration.[54] Second, in addition to a statement of the purpose for which such drug is intended,[55] the FDA should consider requiring a statement specifically noting that the drug is not intended or effective for weight control.[56] Third, the packaging should include a warning that consumers should "Stop use and ask a doctor if" dependence or other common health effects result from overuse.[57]

Even with the addition of appropriate labeling, laxatives may rightly be the focus of access restrictions because some people who abuse laxatives engage in pervasive use despite knowledge of potential harm or experiences with poor health effects because of their underlying disordered eating behaviors.[58–60] Unlike diet drugs, laxatives may be medically appropriate in a situation where time may be of the essence. Therefore, a requirement that laxatives be maintained BTC of pharmacies only may unreasonably hinder healthy users' access when medically needed so less restrictive access restrictions may ultimately be indicated.

If increased labeling alone does not alter consumption patterns, or if an authoritative medical body determines that laxatives should not be used by minors (younger than 18 years) without physician or parental supervision, or that minors are the primary or persistent over-consumers of laxatives, the government might deem it appropriate to regulate access to laxatives. A specific method would be to require that laxatives be sold from BTC in all retail establishments and pharmacies to prohibit the purchase of large quantities at a time. This stipulation could be coupled with an age restriction to limit the quantity purchasable by minors.

Retailers of all types are required to keep certain products behind the counter, such as tobacco for age verification purposes[61] and pseudoephedrine for quantity restrictions.[43] Similar BTC requirements can be instituted for laxatives. Although this would not prevent consumers from purchasing many small quantities from several establishments, such

a restriction could assist in deterring consumption and would relay the message that consuming large quantities of laxatives is harmful to one's health. The revised location would impact only people at risk for abusing them and not those consumers who would purchase the proper amount for the medically indicated use.

CURRENT REGULATIONS FOR ALLI

The FDA approved alli (which is exactly half the dose of the prescription-strength product) for OTC status for weight loss in overweight (defined on the packaging as having a body mass index [BMI, defined as weight in kilograms divided by the square of height in meters] of approximately 27) adults aged 18 years and older.[62] These usage conditions and instructions are disclosed on the product label, including a weight chart for consumer reference. Since its approval, the FDA has required increased warnings related to possible organ damage.[63]

Although alli is approved for overweight adults only, the FDA does not enforce this requirement, and alli can be purchased in retail establishments, pharmacies, and online without age or weight verification. The manufacturer reportedly has requested that retail partners examine the customer's age at time of purchase (L. M. T., telephone interview with Fran Cilella, Customer Sales Manager, GlaxoSmithKline; 2010); however, not all retailers follow this practice,[64] and online Web sites do not check the age of online customers.[65,66] Furthermore, retailers are not requested to determine BMI prior to selling the product to consumers.

Regulations are diverse internationally. In 2009, the European Union approved the switch from prescription to nonprescription for alli for use by adults with a BMI of 28 or higher.[67,68] In the Netherlands, orlistat is OTC pharmacy.[44] In the United Kingdom and Ireland, alli is classified as a BTC pharmacy drug and the onus is on the pharmacists to verify age and determine BMI prior to sale.[19,69,70] The manufacturer and pharmacy societies train the pharmacists in both countries but consumer groups found that a large percent of pharmacists were not verifying BMI prior to dispensing alli. In Australia, orlistat is approved for BTC pharmacy status and indicated for adults 18 to 74 years old with a BMI greater than 30 or a BMI greater than 27 with other serious comorbidities.[44,71,72] The Australia pharmacist professional society recommends pharmacists consider a customer's BMI, waist circumference, and age upon a request for orlistat.[73]

RECOMMENDED REGULATIONS FOR ALLI

Unlike for OTC laxatives, instructions and approved conditions for use are stated on alli's packaging. The label specifically indicates that the product is for adults 18 years old or older and that one should not take the product if one is not overweight or take more than the recommended dose.[62] If studies continue to reveal that alli is a product of abuse, increased warnings may be warranted to educate consumers so they can make informed choices.[33]

In terms of regulating access, alli is the only FDA-approved OTC weight loss aid. However, it has many indications for use that are not enforced in the United States, including age, dosing, and BMI requirements. By simply doubling the dose, consumers could take an equivalent to the prescription product without physician supervision. If evidence of misuse, abuse, or underage use accumulates, the government might consider requiring alli for BTC pharmacy-only status. The BTC designation is most relevant and appropriate for drugs that are prone to abuse or have age restrictions placed on their purchase.[41] BTC status would enable age verification. Pharmacy-only status could encourage customers to consult a pharmacist. This is pertinent because of the risk of persons doubling the dose to obtain the prescription strength amount without physician authorization. Additionally, access to diet drugs is not associated with an immediate need, so BTC pharmacy status would not unnecessarily impede access for a medically approved use.

The literature does not reveal how the pharmacy recommendations to verify BMI in the United Kingdom, Ireland, and Australia have been carried out in practice or how they are enforced. There is a concern of stigmatizing overweight people if pharmacists are required to weigh consumers or otherwise verify BMI. This could inadvertently result in people who would benefit from the weight loss drug not requesting the product to avoid such a measure.

EFFICACY OF RECOMMENDED ACTIONS

The FDA has determined that the disclosure of usage and safety information on OTC drug packaging is important to allow consumers to protect themselves and their families.[74] Research into the effects of warning labels appears in the marketing, policy, and health literature, among other disciplines, and suggests that efficacy varies for different types of products and different outcomes assessed.[75,76] But research does indicate that individuals who read warning messages are more likely to comply with them and that the presence of the warning alone increases the likelihood of hazard reduction even when the danger is known.[75] Importantly, studies show that consumers are likely to underestimate the risks associated with products when a warning is not present.[75] This finding is especially pertinent to OTC laxatives, which carry no precautions or indications of adverse consequences of misuse. In addition, researchers found that adolescents appeared willing to read labels and learn about side effects and dosage requirements.[77]

Despite the necessity of strengthening the warning labels for certain OTC products abused for weight control, risks can sometimes be best reduced by requiring a health care professional to educate consumers or determine proper dispensation criteria.[77] In the context of the products analyzed, BTC placement may be warranted to encourage pharmacist consultation or allow for age verification. Restricting direct-consumer access to products that have potential public health ramifications is a common feature of the US regulatory environment, such as the case of prescription drugs, tobacco, and alcohol.[55] Restricting access in the alcohol context, for example, aims to protect youths from the potentially negative consequences of engaging in a behavior for which they may not be developmentally prepared, and has been found to successfully reduce youth consumption.[78] A similar rationale is

relevant for products that have age requirements for their use and for which young people might not comprehend the long-term health consequences that result from misuse.

CONCLUSIONS

Congress and the FDA can require factual labeling of products to inform consumers and protect public health. Congress, the FDA, and states have the authority to require that OTC products be placed behind counters, and retailers can follow suit on their own volition. The government can also reconsider OTC status for products with enduring public health concerns.

New products that can be abused for weight loss purposes are constantly emerging, and governments have limited resources to address each product piecemeal. Beyond the retail and pharmacy environment, previously banned and other products associated with abuse and health risks are widely available on the Internet. Governments internationally would have to address this situation simultaneously to make any impact. The ability to purchase harmful products on the Internet is not limited to drugs, and the phenomenon is not new. An international effort on this front would be a positive step to protect public health. ■

About the Authors

Jennifer L. Pomeranz is with the Yale Rudd Center for Food Policy and Obesity, Yale University, New Haven, CT. At the time of the study, Lisa M. Taylor was with Harvard Law School, Boston, MA. S. Bryn Austin is with the Division of Adolescent and Young Adult Medicine, Boston Children's Hospital, and the Department of Pediatrics, Harvard Medical School, Boston, MA.

Correspondence should be sent to Jennifer L. Pomeranz, Yale Rudd Center for Food Policy & Obesity, Yale University, 309 Edwards Street, Box 208369, New Haven, CT 06520-8369 (e-mail: jennifer.pomeranz@yale.edu).

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Contributors

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