Use of a Pharmaceutically Adulterated Dietary Supplement, Pai You Guo, Among Brazilian-Born Women in the United States

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BACKGROUND: Pai You Guo is a weight loss supplement manufactured in China and adulterated with the banned pharmaceutical products sibutramine and phenolphthalein. The US Food and Drug Administration (FDA) announced a voluntary recall of Pai You Guo in 2009, yet clinicians have noted its continued use among Brazilian-born women in Massachusetts.

OBJECTIVE: To assess prevalence of Pai You Guo use, associated side effects, modes of acquisition, and impact of FDA regulatory action on these outcomes.

DESIGN: Cross-sectional study using an anonymous questionnaire.

PARTICIPANTS: Women ≤ 60 years of age, born in Brazil who attended one primary care clinic or one of six churches in Massachusetts.

MAIN MEASURES: Prevalence of use, how users first heard about the product, location of purchase, associated side effects, patterns of use before and after the FDA recall.

KEY RESULTS: Twenty-three percent (130/565) of respondents reported using Pai You Guo. In multivariate analysis, obesity (adj OR 3.7, p-value <0.001) and lack of insurance (adj OR 2.6, p-value 0.005) were associated with use. The majority of users (85%) reported at least one side effect. Dry mouth (59%), anxiety (29%), and insomnia (26%) were most commonly reported adverse effects. Nearly thirty-percent of users (38/130) purchased Pai You Guo from local stores and 9% (11/130) purchased it over the Internet. The majority of respondents (79/130; 61%) purchased Pai You Guo after the FDA recall. No respondent was aware of the FDA recall.

CONCLUSIONS: Use of this pharmaceutically adulterated supplement is common among Brazilian-born women in Massachusetts. The FDA alerts and recall did not appear to decrease its use.

KEY WORDS: dietary supplements; women's health; adulterated pharmaceuticals; weight loss.

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Over two thirds of the United States (US) population is overweight or obese¹ and millions of Americans turn to dietary supplements in an attempt to lose weight.^{2,3} However, many weight loss supplements have been found to contain a variety of banned pharmaceutical ingredients, some of which have led to life-threatening adverse reactions and deaths.^{4–6} Since 2005, the US Food and Drug Administration (FDA), as well as European regulatory agencies, have identified over 300 such pharmaceutically adulterated weight loss supplements.^{7,8} A wide variety of banned compounds have been identified including sibutramine, cetilistat, rimonabant, fenproporex, phenolphthalein, and many others.⁴ Despite the potentially serious health risks, very little is known about the prevalence, distribution or common adverse effects of pharmaceutically adulterated supplements.

Pai You Guo is a dietary supplement marketed for weight loss that the FDA found to contain the banned pharmaceutical compounds sibutramine and phenolphthalein.^{9–11} Sibutramine was withdrawn from the US market in September, 2010 because of increased risk of heart attack and stroke,¹² and phenolphthalein was withdrawn as an over-the-counter laxative in 1997 due to its potential carcinogenic properties.¹³ The FDA has analyzed Pai You Guo sold in Florida, California and Washington state and detected up to 27 mg of sibutramine in individual capsules¹⁴ and 30 mg in packets of tea,¹⁵ two to six times more sibutramine than in formerly available prescription capsules.

Pai You Guo is manufactured in China and sold as a capsule or tea for weight loss. Although many herbal ingredients are listed on the packaging, we are unaware of any herbal ingredients being identified within the capsules or tea. Pai You Guo which means ‘the fruit that sheds the fat’ in Mandarin Chinese has no traditional uses. In late 2009 the FDA took multiple steps to address the risks posed by Pai You Guo: a safety alert to consumers; an import alert to custom officials to prevent importation of Pai You Guo; and announced a recall of Pai You Guo by its US distributor.¹⁶ Despite the FDA recall, The Boston Globe reported continued sales of Pai You Guo in Massachusetts stores at \$20 for a month's supply.¹⁷

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We conducted a study among Brazilian women in Massachusetts to better understand how commonly Pai You Guo is used, what adverse reactions are experienced, where it is obtained, what users understand about its potential effects on health, and the impact of the FDA requested recall in 2009 on these outcomes. Young to middle-aged Brazilian women were selectively studied because of their previously documented high prevalence of use of alternative diet pills¹⁸ and clinicians' anecdotal reports of Pai You Guo use in this community.¹⁷

METHODS

Study Design, Recruitment and Participants

Between mid-October, 2010 and mid-January, 2011 we surveyed women from one internal medicine primary care clinic in Somerville, Massachusetts and six Brazilian churches in the Greater Boston metropolitan area (i.e. Allston [1 church], Medford [2 churches], Chelsea [1 church], Watertown [1 church], and Saugus [1 church]). The clinic was selected because over half of its patients are Brazilian immigrants and anecdotal clinical observations suggested that Brazilian women at this clinic were using Pai You Guo. The churches were selected because of their large Brazilian populations and preexisting relationships with our integrated healthcare system through a program of Brazilian volunteer outreach workers (not involved in this study).

Study inclusion criteria at the clinic were being female, born in Brazil, age 12 to 60 years old, and presenting to clinic for any type of visit with a physician, nurse, pharmacist, social worker or lab technician. If a woman arrived in clinic but did not have a scheduled appointment, she was not eligible for the study. A study coordinator reviewed the schedule of patients before the start of each clinic session and noted the gender, age and language spoken and, based on study entry criteria, placed a reminder in the electronic medical record of each patient that was potentially eligible for the study. A reminder was placed in the record of all Portuguese-speaking women and women with English as their preferred language if she had a Portuguese given name or surname. The front desk staff then queried these women to assess eligibility at the time of the visit. Eligible patients were asked by the administrative staff to complete the survey described as a "health habits" survey. A study coordinator was also available to answer any questions that eligible women had about the survey. No incentives were offered for completing the survey in the clinic.

To recruit our community sample, the study coordinator, with the permission of presiding priests, attended five masses at different churches as well as a women's faith gathering at a sixth church during the study period. All women attending the church masses or gathering were asked their age and if they were born in Brazil. All women born in Brazil who were 12 to 60 years of age were invited to complete the "health habits" survey. At the churches, women who completed a survey were entered into a raffle for a \$30 gift certificate for a local supermarket as an incentive to participate.

The study was reviewed and approved by the Cambridge Health Alliance's Institutional Review Board.

Survey Design and Content

Data were collected using a self-administered anonymous paper survey. Women could choose to complete the survey either in Portuguese or in English. Survey development was guided by interviews with patients, healthcare providers, community members, Brazilian interpreters and community organizers with knowledge of the Brazilian community's use of diet pills. We were particularly careful to refer only to Pai You Guo, both pills and tea, in survey questions regarding use and to distinguish this product from any other weight loss pills or supplements. A photograph of the Pai You Guo packaging was included in the survey to clearly identify it to participants. Survey questions were developed in English and then translated by a professional medical interpreter into Portuguese. The survey was pilot tested with Brazilian women and their feedback informed the final survey design.

The survey instrument consisted of 20 questions. Respondents were asked to report their age, sex, marital status, height, weight, total number of years they had lived in the US, level of school they had completed, insurance status, and annual income. They were asked whether they had ever used Pai You Guo. If the respondent had ever used Pai You Guo, they were asked to complete seven questions, including how they initially learned about the product, where it was purchased, when it was first purchased, when it was last purchased, whether they lost weight while using it, whether they were aware of the potential health effects of it and, if so, how they learned of those health effects. In addition, respondents were asked about the side effects they experienced while taking Pai You Guo by selecting one or more side effects from a list of 15 common side effects. Respondents could also select 'other' which provided space to write in additional side effects, or select 'no side effects'. Because height and weight were not measured as part of this study, we used respondents' self-reported height and weight to calculate their body mass index (BMI). Using World Health Organization definitions, we defined underweight as BMI <18.5, normal weight BMI 18.5-24.99, overweight BMI 25-29.99 and obese BMI ≥30.¹⁹

Statistical Analyses

How respondents first learned about the supplements, the timing and location of purchase and reported side effects were analyzed with simple descriptive statistics. To determine if any clinical or demographic factors were associated with the use of Pai You Guo, we conducted bivariate analyses comparing respondents that indicated that they had used Pai You Guo ("users") with those indicating they had not ("non-users") with regard to sociodemographic variables and BMI using means and associated t-tests for continuous variables and chi-square tests for categorical variables. We calculated unadjusted odds ratios and 95% confidence intervals for the use of Pai You Guo for each of these variables. Finally, to identify factors independently associated with Pai You Guo use, we fit a logistic regression model that included only factors that remained in

the model after using a stepwise selection scheme to identify variables that were statistically significantly associated with use at the $p < 0.05$ level. The only variables that remained in the final model were insurance status and BMI.

The FDA announced the recall of Pai You Guo in November, 2009 and, thus, we considered purchases in 2009 or earlier to be before the FDA recall and purchases in 2010 to be after the FDA recall. In order to assess whether the FDA recall had an impact on where Pai You Guo users first heard about this product, where it was purchased and awareness of its potential health effects, we compared each of these outcomes according to whether it occurred before 2010 versus in 2010. We used two-sided χ^2 tests with an a priori level of significance of $P < 0.05$ to test for all of the above associations.

RESULTS

Of 677 eligible women, 587 (87%) completed the survey. Almost all surveys, 98.8% (580/587), were completed in Portuguese. Of the eligible women, 81% (319/337) at the clinic and 94% (268/284) at the churches completed surveys. Subsequently, 22 surveys (3.7%) were excluded because the respondent did not provide information about age, country of origin, gender, or use of Pai You Guo, yielding a final sample of 565 (255 from the community and 310 from the clinic). Table 1 summarizes respondents' sociodemographic characteristics.

Overall prevalence of Pai You Guo use was 23% (130/565). How respondents first learned about Pai You Guo, the timing and location of purchase and reported side effects are

Table 1. Characteristics of the Study Sample

Characteristic	Total (n=565) n (%)
Age in years	
Mean (SD)	39.0 (9.7)
12-30	127 (22.5)
31-45	271 (48.0)
46-60	167 (29.6)
Married	
Yes	356 (64.6)
Length of time in United States (US)	
≤5 years	83 (14.7)
>5 years	482 (85.3)
Education	
Less than high school	121 (21.5)
High school graduate	317 (56.2)
College graduate	126 (22.3)
Insured	
Yes	490 (91.9)
Body mass index	
Mean (SD)	26.1 (6.7)
<18.5	77 (13.6)
18.5-24.9	250 (44.2)
25.0-29.9	137 (29.6)
≥30	101 (17.9)
Annual income	
\$0-9,999	77 (16.2)
\$10,000-24,999	196 (41.4)
\$25,000-39,999	90 (19.0)
≥\$40,000	111 (23.4)

SD, standard deviation

summarized in Table 2. Most users (84%) first heard about Pai You Guo from a friend or family member. A significant minority learned about Pai You Guo from the radio (11%) or a local US store (9%). Pai You Guo was purchased from an acquaintance (66%), at a store (30%) and over the Internet (9%). The majority of Pai You Guo users (56%) lost weight while taking the supplement. The vast majority of Pai You Guo users (85%) reported experiencing at least one side effect during use. The most commonly reported side effects were dry mouth (59%), anxiety (29%) and difficulty sleeping

Table 2. Use of Pai You Guo: Sources, Timing of Purchase and Awareness of and Experiences of Adverse Effects

	Total (n=130) n (%)
First heard about Pai You Guo*	
Friend/family member	109 (83.9)
Radio	14 (10.9)
Local US store	12 (9.3)
Newspaper or magazine	3 (2.3)
Other	3 (2.3)
Internet	2 (1.6)
Television	0 (0)
Purchase source*	
Acquaintance in US	81 (65.8)
Store in US	38 (29.9)
Internet	11 (8.8)
Other	10 (7.9)
Date of first use	
Pre-FDA announced recall (2009 or earlier)	71 (54.6)
Post FDA announced recall (2010)	59 (45.4)
Date of last purchase	
Pre-FDA announced recall (2009 or earlier)	50 (38.8)
Post FDA announced recall (2010)	79 (61.2)
Aware of potential adverse health effects	
Yes	37 (28.7)
Source of health effects information*	
Friend or family member	41 (68.3)
Radio	8 (13.3)
Health care provider	6 (10.0)
Television	6 (10.0)
Internet	4 (6.7)
Newspaper or magazine	1 (1.7)
FDA alert	0 (0)
Side effects*	
Dry mouth	73 (59.4)
Anxiety	35 (29.2)
Difficulty sleeping	31 (25.6)
Palpitations	27 (22.3)
Headache	25 (20.7)
Nausea/vomiting	23 (19.2)
Perspiration	17 (14.1)
Fatigue	12 (9.9)
Depression	12 (10.0)
Heartburn	11 (9.2)
Constipation	7 (5.8)
Fainting	6 (5.0)
Visual changes	3 (2.5)
Feeling addicted	3 (2.5)
Other	12 (9.2)
No side effects	19 (15.2.)
Any side effects	106 (84.8)
Weight loss with Pai You Guo use	
Yes	71 (55.5)

*Sum of percentages exceeds 100% because participants marked multiple responses

US, United States

FDA, U.S. Food and Drug Administration

(26%). Two and a half percent of users reported feeling addicted to Pai You Guo. Less than one third of users were aware of potential adverse health effects related to Pai You Guo (Table 2). Forty-five percent of users first purchased Pai You Guo after the recall, and 61% of users made their last purchase of Pai You Guo after the recall (Table 2). None of the respondents were aware of the FDA alert.

Factors associated with Pai You Guo use are summarized in Table 3. Overweight women were more than twice as likely (adjusted odds ratio =2.5, 95% CI=1.5 to 4.3) and obese women were more than three times as likely (adjusted odds ratio OR=3.7, 95% CI=2.1 to 6.4) to use Pai You Guo than women with a normal BMI. Respondents who were uninsured were more than twice as likely to have used Pai You Guo than insured women (adjusted odds ratio =2.6, 95% CI=1.3 to 5.1). These associations changed little in the multivariate model. No other factors we examined were associated with increased use.

We compared how respondents first learned about the supplements, the timing and location of purchase, as well as reported side effects between respondents who first purchased Pai You Guo before the FDA recall and those who first purchased it after the FDA recall. The percentage of users who first heard about Pai You Guo from a commercial or media source was 17% (12/71) before the recall and 29% (17/59) after the recall. The percentage of users who purchased Pai You Guo at a store in the US was 31% (22/71)

before the recall and 23% (13/59) after the recall. Pai You Guo was purchased over the Internet by 8.6 % (6/71) before the recall and 8.8% (5/59) after the recall. The percentage of Pai You Guo users who had heard about the potential health effects of Pai You Guo was 34% (24/71) before the recall and was 22% (13/59) after the recall. None of these changes were statistically significant.

DISCUSSION

We found in one community of Brazilian young to middle-aged women in the US that more than one in five women (23%) had used Pai You Guo, a weight loss supplement that is adulterated with pharmaceutical compounds known to cause serious cardiovascular and cerebrovascular events. The vast majority (85%) of respondents reported side effects while taking the supplement. Despite the FDA announced recall in 2009 and the issuance of two alerts, the majority of users (61%) purchased this supplement after the recall.

The high prevalence of Pai You Guo use we observed is a significant clinical and public health concern because any use of this product may be dangerous. Even when sibutramine is formulated under stringent pharmaceutical quality controls it can lead to serious adverse effects including heart attacks,

Table 3. Patient Demographic and Clinical Characteristics Associated with Pai You Guo (PYG) Use

Characteristic	Pai You Guo Users (n=130)	Pai You Guo Non-Users (n=435)	P-value	Unadjusted OR* for Pai You Guo Use (95% CI)	P-value	Adjusted OR for Pai You Guo Use (95% CI)	P-value
	n (%)	n (%)					
Age, years							
Mean (SD)	37.7 (9.2)	39.4 (10.2)	0.09				
12-30	35 (26.9)	92 (21.2)		1.6 (0.9-2.7)		–	
31-45	62 (47.7)	209 (48.0)	0.29	1.2 (0.8-1.9)	0.29	–	
46-60	33 (25.4)	134 (30.8)		Ref			
Married			0.52		0.52		
Yes	85 (65.4)	271 (62.3)		Ref		–	
No	45 (34.6)	164 (37.7)		1.1 (0.8-1.7)		–	
Time in US			0.80		0.80		
≤5 years	20 (15.4)	63 (14.5)		1.1 (0.6-1.9)		–	
> 5 years	110 (84.6)	372 (85.5)		Ref		–	
Education			0.60		0.60		
<High school	26 (20.0)	95 (21.9)		1.1 (0.6-1.9)		–	
High school graduate	78 (60.0)	239 (55.1)		1.2 (0.8-2.1)		–	
College graduate	26 (20.0)	30 (23.0)		Ref		–	
Insurance			0.003		0.004		0.005
Yes	108 (85.7)	382 (93.9)		Ref		Ref	
No	18 (14.3)	25 (6.2)		2.6 (1.3-4.8)		2.6 (1.3-5.1)	
BMI†							
Mean (SD)	28.2 (5.8)	25.5 (6.8)	<0.001				
<18.5	11 (8.5)	66 (15.2)		0.93 (0.5-1.9)	<0.001	1.2 (0.6-2.4)	
18.5-24.9	38 (29.2)	212 (48.7)	<0.001	Ref		Ref	<0.001
25.0-29.9	43 (33.1)	94 (21.6)		2.6 (1.6-4.2)		2.5 (1.5-4.3)	
≥30	38 (29.2)	63 (14.5)		3.3 (2.0-5.8)		3.7 (2.1-6.4)	
Annual income			0.76		0.76		
\$0-\$9,999	17 (13.6)	60 (17.2)		0.73 (0.37-1.4)		–	
\$10,000-\$24,999	51 (40.8)	145 (41.6)		0.91 (0.5-1.5)		–	
\$25,000-\$39,000	26 (20.8)	64 (18.3)		1.1 (0.6-1.9)		–	
≥ \$40,000	31 (24.8)	80 (22.9)		Ref		–	

*OR, odds ratio

†BMI, body mass index

SD, standard deviation

CI, confidence interval

strokes and acute psychosis.^{20,21} When produced by illicit manufacturers its risks likely increase due to variable quality and dosages. Dosages of pharmaceutical products in adulterated supplements range widely, and the FDA has found up to 27 mg of sibutramine in individual Pai You Guo capsules¹⁴ and 30 mg in packets of tea,¹⁵ which is significantly higher than the previously available 5 to 15 mg prescription capsules. When sibutramine and phenolphthalein are consumed unwittingly, patients may experience unexpected side effects or drug-drug interactions. Concerned physicians, unaware of supplement use or its potential risks, could mistake side effects as symptoms of other illnesses leading to unnecessary diagnostic evaluation and treatment.^{22,23}

We found that the high prevalence of Pai You Guo use did not vary by age, marital status, length of time in the US, education or income but, not surprisingly, was more common among overweight and obese women than normal weight women. Lack of health insurance was also associated with greater likelihood of supplement use and may suggest that a higher proportion of uninsured women seeking obesity treatment opted for Pai You Guo since it is available without the additional expense of seeing a physician.

To our knowledge our study is the first to provide data on the distribution methods of a FDA identified pharmaceutically adulterated dietary supplement. One out of every five consumers first heard about Pai You Guo from a commercial source (i.e., radio or store) and slightly less than a third of users purchased the product at local stores. Only 9% of users purchased Pai You Guo over the Internet. These surprising results suggest that the Internet may play a smaller role than previously assumed in the sales of adulterated weight loss supplements. Future research should address how international manufactures of these illegal products are able to distribute their products so effectively using traditional commercial outlets in the US. Purchases from individuals or at local stores, rather than anonymously over the Internet, may have the effect of increasing sales by legitimizing these products and providing a false sense of security to prospective consumers.

In this study population the FDA alerts and recall had little discernable effect on consumers' habits. We found that the majority of respondents (61%) purchased Pai You Guo after the FDA announced recall. No respondent was aware of the FDA alerts. These findings may indicate that lower income, immigrant populations with low English language proficiency may be difficult to reach with information about the safety of supplements such as Pai You Guo. Alternatively, our findings may point to a more fundamental problem with the federal government's inability to regulate pharmaceutically adulterated weight loss supplements.

Our study has several limitations. We sampled only Brazilian immigrant women ≤ 60 years old in one geographic community and distribution networks may differ in other populations and communities. In addition, we studied only one adulterated weight loss supplement. It is possible that other adulterated supplements are marketed, distributed and used in different manners. Future research is required to determine if our findings are generalizable to other populations and geographic areas as well as to other adulterated supplements. Furthermore, our study did not perform chemical analyses of samples of Pai You Guo. It is possible that pharmaceutical adulteration is variable and that these capsules might combine pharmaceutical products with herbal ingredients. However, the FDA has found

pharmaceutical levels of sibutramine in Pai You Guo throughout the US and requested a recall of the product due to serious safety concerns, therefore any sales or consumption of Pai You Guo should raise significant health concerns. Finally, our study relied on self-reported data. Self-reported data may have led to underreporting of Pai You Guo use due to social stigma associated with use of nonprescription weight loss products. Self-reporting of height and weight is not as accurate as measured height and weight but should accurately reveal trends such as our finding that the prevalence of Pai You Guo use increases with increasing BMI.

Our study should raise concerns about the potential negative health effects of Pai You Guo in a significant percentage of the population we studied and, if our results are generalizable, a significant proportion of the public. It should also raise significant concern about the current regulatory framework governing Pai You Guo, and perhaps adulterated dietary supplements more generally. Improved physician awareness about the use of this supplement could help limit their patients' consumption of this potentially dangerous supplement. Greater regulatory authority that would allow the FDA to require demonstration of purity, quality and safety of supplements prior to marketing and greater resources devoted to prosecuting the criminals who profit from the sales of adulterated weight loss supplements would likely diminish exposure to harmful supplements throughout the US.

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