

Illicit Online Marketing of Lorcaserin Before DEA Scheduling

Bryan A. Liang^{1,2,3,4}, Tim K. Mackey^{1,3,4,5}, Ashley N. Archer-Hayes⁴ and Linda M. Shinn^{4,6}

Objective: Antiobesity drugs have been marketed illicitly by “no prescription” online pharmacies after approval and scheduling by the drug enforcement agency. We assess whether antiobesity drug Belviq[®] (lorcaserin HCl) was available from illicit online vendors before DEA-scheduling when sales are unauthorized.

Design and Methods: Online searches of “buy Belviq no prescription” examining first five result pages marketing the drug. Searches were performed from 11/5/2012-12/8/2012, prior to DEA scheduling.

Results: Belviq[®] is actively marketed by “no prescription” online vendors despite official unavailability and prescription requirements. Approaches included direct-to-consumer advertising using descriptive website URLs; linking to illicit marketers; and directing customers to other weight-loss websites for additional marketing. Finally, large quantities were marketed by business-to-business vendors.

Conclusion: Illicit online “no prescription” pharmacies are marketing unauthorized, suspect antiobesity drugs before DEA scheduling and permitted marketing. Regulators must legally intercede to ensure patient safety, and providers must educate patients about online-sourcing risks.

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Background

Obesity is now a global health crisis affecting more than 1.4 billion adults above age 20 (1). Obesity’s growing prevalence has led to pharmaceutical development, but with a mixed patient safety history, including market withdrawal of dexfenfluramine and sibutramine, and removal of phenylpropanolamine (PPA) from all over-the-counter weight loss products (2,3).

However, in June 2012, for the first time in >13 years, the Food & Drug Administration (“FDA”) approved two new medications for long-term treatment of obesity, Qsymia[™] (phentermine topiramate ER) and Belviq[®] (lorcaserin HCl). While Belviq[®] is FDA-approved, at the time of this work, it was not yet legally on the market since post-FDA approval but before marketing, a manufacturer must obtain drug scheduling by the drug enforcement agency (“DEA”) before any marketing and sales may occur. DEA has published a regulatory notice recommending that Belviq[®] be classified as a

Schedule IV controlled substance; however final scheduling designation is still forthcoming.

This set of circumstances provided a unique opportunity to determine if Belviq[®], an approved but not yet legally marketed drug and the time of this study, was being illicitly marketed for sale over the Internet. Alarming, weight-loss drugs have already been identified as the target of counterfeiting and illicit online sales (4-6).

We used Google, Bing and Yahoo! search engines to search “buy Belviq no prescription,” as they are the top three search engines by unique monthly visitors. Qsymia[™] was not included in searches as it has already received DEA scheduling and can be legally marketed by authorized providers. For each of the searches, we examined the first five pages of results and examined websites that marketed an offer of sale, a search strategy used in previous studies (7,8). Searches were performed from 11/5/2012-12/8/2012, prior to DEA scheduling of Belviq[®]. Ethical and legal concerns regarding

¹ Institute of Health Law Studies, California Western School of Law, California, USA. Correspondence: Bryan A. Liang (baliang@alum.mit.edu) ² San Diego Center for Patient Safety, University of California San Diego School of Medicine, California, USA ³ Department of Anesthesiology, University of California San Diego School of Medicine, California, USA ⁴ Joint MAS Program in Health Policy, University of California, San Diego-California Western School of Law, California, USA ⁵ Joint Doctoral Program on Global Health, University of California San Diego-San Diego State University, California, USA ⁶ Staff Nurse, Department of Labor and Delivery, Naval Hospital Camp Pendleton, California, USA

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TKM is also the 2011-2012 Carl L. Alsberg, MD, Fellow of the Partnership for Safe Medicines, the latter of which is not connected with the submitted work. BAL, TKM, Ashley N. Archer-Hayes, and Linda M. Shinn have no other relationships or activities that could appear to have influenced the submitted work.

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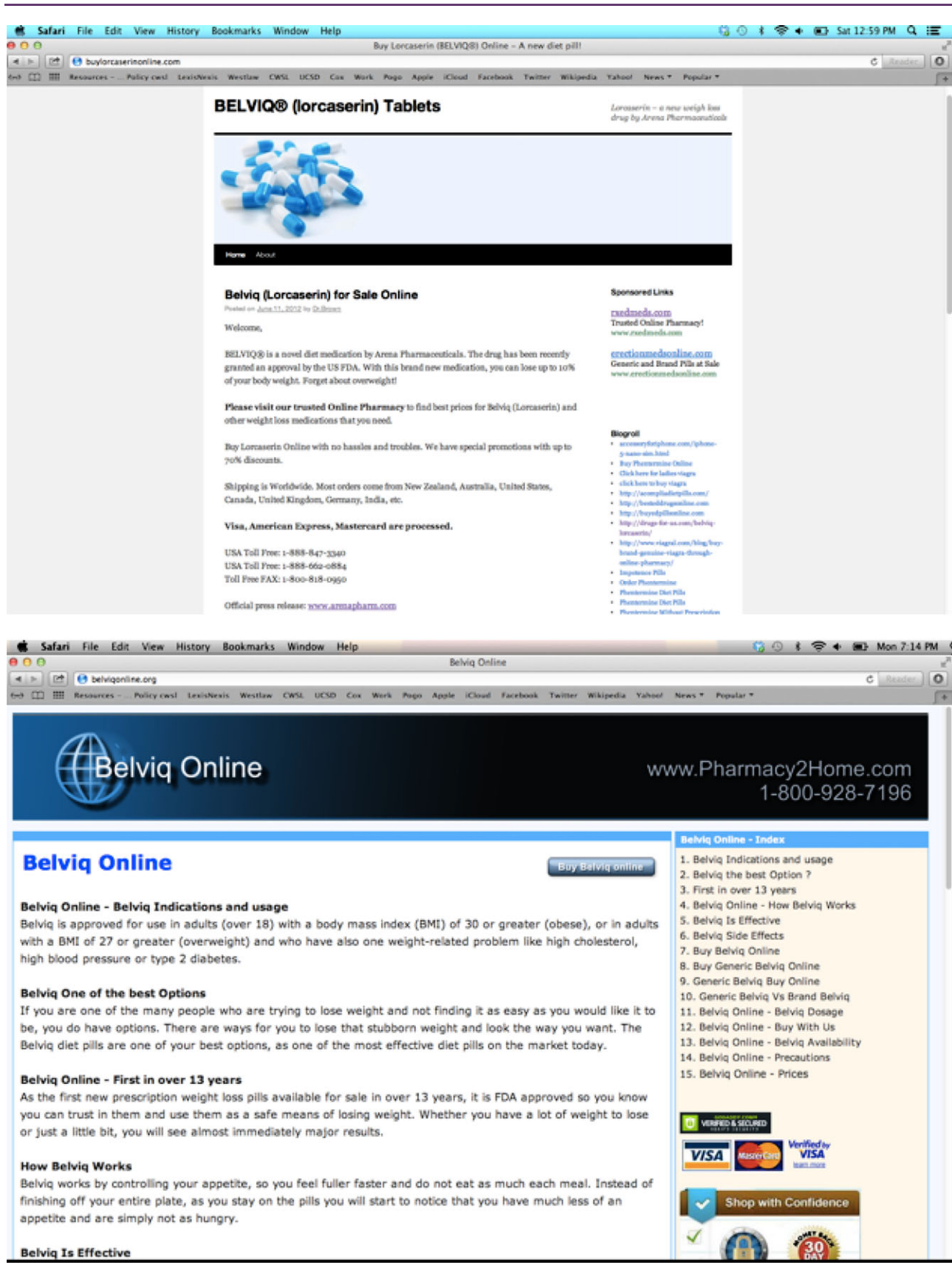


FIGURE 1 Illicit marketing of Belviq (lorcaserin) online.

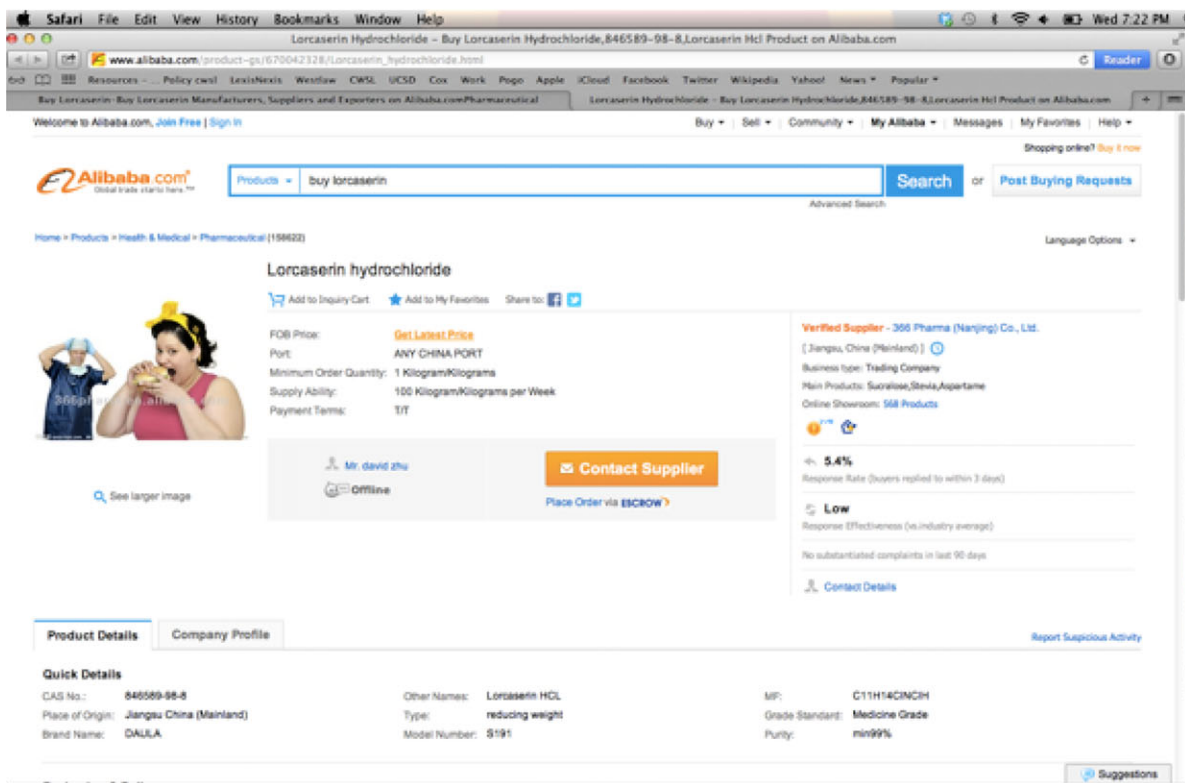
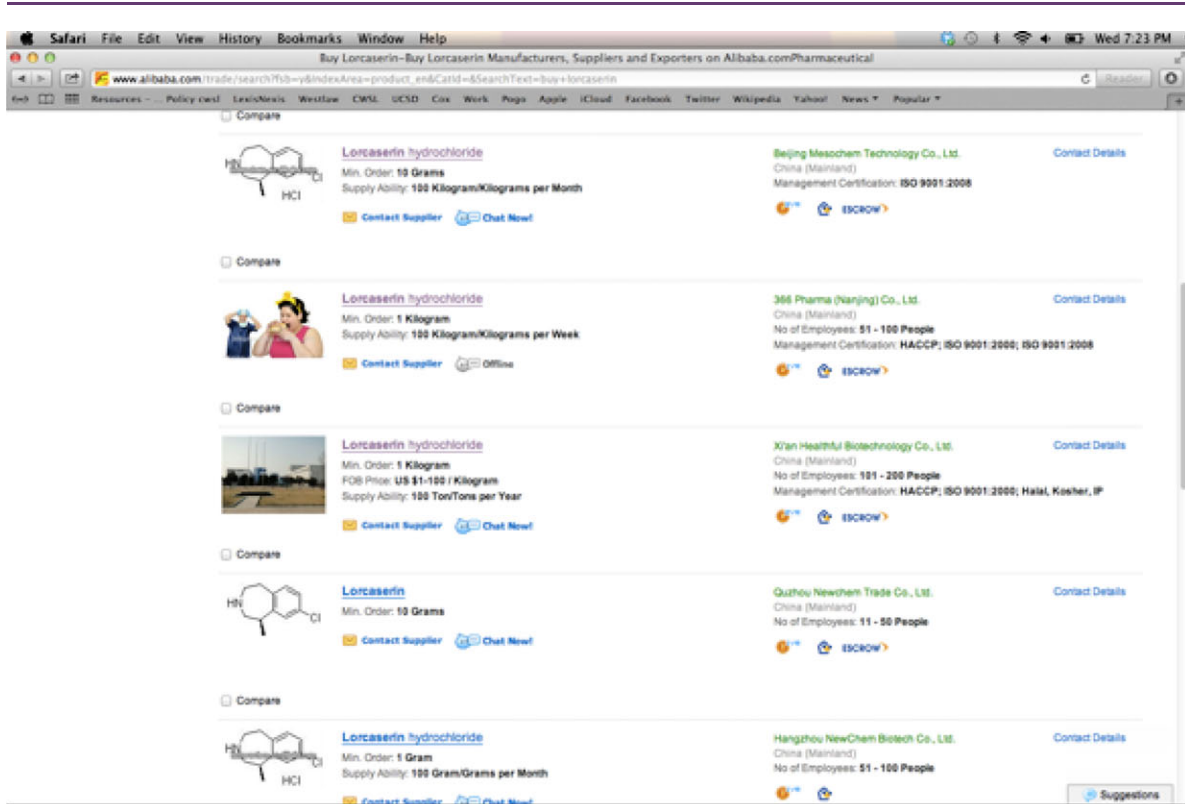


FIGURE 2 Alibaba.com business-to-business search results.

falsifying patient information and purchasing online without a prescription prohibited us from actual purchase of drugs purportedly marketed for sale as Belviq[®], though other studies have identified counterfeit weight-loss medications from online purchasing (4).

Online Findings

We found Belviq[®] actively marketed by “no prescription” online vendors despite its official unavailability in the USA and its requirement for dispensing only with a valid prescription (Figure 1). All search engines found the same sites illegally marketing Belviq[®].

We found illicit marketing approaches focused on direct-to-consumer advertising (DTCA) using descriptive website names (e.g., buybelviqonline.com), which then provided links to illicit websites marketing the drug (Figure 1). Strategies included prominently advertizing “Belviq and lorcaserin,” but instead displaying images of approved drug Qsymia[™] or redirecting to other weight-loss drug websites. This may be a marketing tactic to confuse the buyer who believes he/she is purchasing Belviq[®], which is misrepresented as an FDA-approved drug, into other potentially unapproved diet products.

We also found illicit sellers were highly responsive to marketing changes promoting the appearance of legitimacy. A color change to Belviq[®]'s logo occurred during this study. The official logo was originally a bluish/purple color and changed to peach in 11/2012. The illicit website buy-belviq.net updated the logo on their site immediately to reflect the change.

Because of these findings, we wished to see if Belviq[®] could be purchased in bulk. We searched Alibaba.com, the world's largest online wholesale trading platform for small businesses. The search “buy Belviq” was automatically changed to “buy lorcaserin” so all Belviq[®] traffic is directed to overseas sellers using a site-wide common search term (Figure 2). Lorcaserin hydrochloride/Belviq was marketed as available from multiple sellers, including in large bulk (e.g., 100 kg week⁻¹).

Discussion

Belviq[®] is actively being marketed for sale from suspect “no prescription” illicit online vendors before DEA-scheduling, making any purported availability highly suspect. This work extends previous studies indicating a wide range of prescription drugs illicitly marketed by online pharmacies direct-to-consumer, representing a clear patient safety risk (7–9).

There are well known patient safety issues with sourcing drugs online, with domestic and global public health agencies, such as FDA and the World Health Organization, issuing warnings (10). Prospective consumers who may purchase online without a prescription risk consumption of counterfeit or otherwise substandard drugs, drug–drug interactions and unknown clinical contraindications, and financial fraud (10).

Indeed, weight loss drugs have been the target of counterfeiters. For example, counterfeit versions of FDA-approved weight loss drug,

Xenical[®] (Orlistat) were found to be sold by multiple Internet vendors in 2007 (5). Laboratory analysis revealed the capsules actually contained sibutramine, the wrong active ingredient and a dangerous drug withdrawn from the USA market (5). Other instances include the 2010 FDA warning of counterfeit over-the-counter drug Alli, which also contained sibutramine as the wrong ingredient (6).

To address potential supply-side issues, FDA in cooperation with the Department of Justice and the Federal Trade Commission should identify these websites and act to close them immediately. Using a legal approach called the Park Doctrine, corporate owners and other responsible officials can be held liable for misdemeanors without proof these persons acted with criminal intent, negligence, or even knowledge. In this case, misdemeanor prosecutions for Food, Drug & Cosmetic Act violations, including unapproved drug marketing and sales, automatically create felonies for any subsequent violation. These felony prosecutions also do not require proof of intent, and could be applied to illicit online marketing and sale of approved but unscheduled drugs.

Patient education is also an important to address demand-side concerns. We believe that providers must educate patients about online drug risks, as patients themselves represent a key barrier to harm. Further, we believe search engine warnings should be employed to countermarket or remove clearly illicit “no prescription” online marketing.

Obesity is a significant and global health burden. Pharmaceutical interventions may represent an important component of treatment. Yet illicit marketing and limited oversight of suspect online activity creates significant patient safety risks. As the digital marketplace grows, so will the appetite of illegal online marketers seeking to profit by selling suspect antiobesity treatments. **○**

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