

FDA Should Restrict E-cigarette Marketing to Protect Youth as Part of the Currently Proposed Regulation

Docket No. FDA-2014-N-0189

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From 2004 to 2009, US 14- to 17-year-olds who did not smoke cigarettes but used an alternative tobacco product (smokeless tobacco, cigars, pipes, bidis, or kreteks) exhibited nicotine dependence symptoms comparable to those of cigarette smokers.¹ Because most e-cigarettes contain nicotine at variable levels, similar patterns are likely to emerge among youth e-cigarette smokers. The FDA must regulate the marketing of e-cigarettes in order to prevent a new generation of youth addicted to nicotine. The proposed FDA rule fails to include effective restrictions on the marketing of these nicotine-delivery devices. Waiting to issue such regulations as part of a later rule will delay implementation of effective regulation for years, with the attendant costs of more youth becoming addicted to nicotine and suffering the health consequences of using the products the FDA proposes to regulate.

E-cigarette advertisements target youth

Tobacco remains the leading cause of death and disease in the US, and the Secretary of HHS said that the proposed rule is the “latest step in our efforts to make the next generation tobacco-free.”² Even though the proposed rule would institute a minimum age of 18 for purchasing newly covered products including e-cigarettes, the rule will not combat the tobacco epidemic if it does not also prohibit the marketing of these products to youth. **Age limits on e-cigarettes will be ineffective without advertising restrictions.**

The FDA proposed rule cites the scientific evidence that because youth are particularly vulnerable to the appeal of potentially addictive novel tobacco products, and youth become addicted to nicotine more easily and earlier than adults,^{3,4} these products “can introduce youth into a lifetime of addicted tobacco product use and related harms, including premature death” (p.23146). Sales of e-cigarettes in the US are expected to top \$10 billion by 2017.⁵ In April 2014, members of the House and Senate released a report showing that e-cigarette companies are aggressively promoting their products to young people.⁶ In May 2014, the Legacy Foundation,

¹ Saunders C, Geletko K (2012). Adolescent cigarette smokers' and non-cigarette smokers' use of alternative tobacco products. *Nicotine Tob Res*; 14(8):977-85² FDA News Release (2014). FDA proposes to extend its tobacco authority to additional tobacco products, including e-cigarettes. April 24, 2014.

² FDA News Release (2014). FDA proposes to extend its tobacco authority to additional tobacco products, including e-cigarettes. April 24, 2014.

³ DiFranza, J. R., et al. (2008). "Time to re-examine old definitions of nicotine dependence." *Nicotine & tobacco research*10(6): 1109-1111.

⁴ Scragg, R., et al. (2008). "Diminished autonomy over tobacco can appear with the first cigarettes." *Addictive Behaviors*33(5): 689-698.

⁵ Herzog, B and Gerberi, J (2013). *E-cigs revolutionizing the tobacco industry Equity Research*. New York: Wells Fargo Securities.

⁶ Senate and House Report (April 14, 2014). *Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth*. Available at: http://www.durbin.senate.gov/public/index.cfm/files/serve/?File_id=81d14ff7-f2f6-4856-af9d-c20c0b138f8f

created to educate youth about the risks and consequences of tobacco use, released a report with similar findings.⁷

As reported in a published systematic content analysis of e-cigarette website marketing:⁸

"Candy, fruit, and coffee flavors were offered on most sites. Youthful appeals included images or claims of modernity (73%); increased social status (44%); enhanced social activity (32%); romance (31%); and use by celebrities (22%)."

Even tobacco companies and e-cigarette manufacturers admit that flavored e-cigarettes are a problem because of their appeal to youth. In fact, Lorillard, makers of Blu, warned parents on "Real Parents. Real Questions", a subsite of Lorillard's Youth Smoking Prevention Program website, that "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry."⁹ The company also noted "For the first time, 'smoking' ads are returning to TV with advertising campaigns for e-cigarettes" and "More than 1.78 million middle school and high school students have tried e-cigarettes since 2012." Lorillard's Real Parents. Real Questions website also stated that the "Use of e-cigarettes has recently doubled among teens with 4.7% using them in 2011 and 10% using them in 2012." These estimates are for US high school students in the National Youth Tobacco Survey (NYTS). NYTS estimates ever e-cigarette use prevalence among middle school students was 1.4% in 2011 and 2.7% in 2012¹⁰. Current e-cigarette use for both middle and high school students was 1.1% in 2011 and 2.1% in 2012.

Given that e-cigarette companies (which are increasingly owned by large tobacco companies) are using well-established advertising techniques that have been shown to increase tobacco use by youth, it is crucial that the FDA regulate and restrict the marketing of e-cigarettes in the same way that cigarette marketing is restricted as part of the current rule making process.

Similar to cigarettes, e-cigarettes advertisements should be banned in magazines with a 10% or higher youth readership and banned on television and radio. The Settlement Agreement between RJ Reynolds and the State of California in 2004,¹¹ which implemented the Master Settlement Agreement, recommended a figure of 15%, but 10% is more appropriate because research revealed that the 15% restriction is too permissive and still allows high levels of youth exposure to advertising.^{12,13}

⁷American Legacy Foundation, (May 2014). *Vaporized: E-Cigarettes, Advertising, and Youth*. Available at:

http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf

⁸Grana R, Ling P (2014). Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*;46(4):395-403.

⁹ Lorillard Inc. Youth Smoking Prevention Program. Real Parents Real Questions (2014). <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>

Accessed May 31, 2014. (A copy of this website has been submitted to the FDA as a public comment, tracking number 1jy-8cep-qnbq)

¹⁰ Corey C, Wang B, Johnson SE, et al. Electronic cigarette use among middle and high school students- United States, 2011-2012. *Morbidity and Mortality Weekly Report*. 2013;62(35):729-730.

¹¹ Settlement Agreement, 22 December 2004, <http://ag.ca.gov/newsalerts/cms04/04-147.pdf> (accessed 18 March 2008).

¹² Alpert, H.R., et al. (2008). After the Master Settlement Agreement: Targeting and exposure of youth to magazine tobacco advertising. *Health Affairs*, 27 (6): w503-w512.

¹³ Hamilton, W.L., et al. (2002). Cigarette advertising in magazines: the tobacco industry response to the Master Settlement Agreement and to public pressure. *Tobacco Control*, 11(Suppl. II): ii54-ii58.

The FDA should also prohibit the use of marketing techniques that are known to attract youth, which include flavors and cartoons.

The 2012 Surgeon General's Report on preventing adolescent tobacco use concluded that youth exposure to tobacco cigarette advertising *causes* youth smoking.¹⁴ As noted above, e-cigarette advertising uses the same appeals that cigarette companies have used to entice kids into a lifelong addiction to cigarettes.^{15,16,17} These include:

- widespread marketing of fruit, candy, mint and even alcohol flavors (Figure 1)
- romantic or sexual imagery (Figure 2)
- celebrity endorsements (Figure 3)
- event sponsorships (Figure 4)
- social media (Figure 5)

Spending on advertising rising from \$5.6 million in 2010 to \$82.1 million in 2013.⁹

Unlike cigarette companies, e-cigarette companies are currently free to advertise their products in magazines, on television and radio, and in other media outlets that have a youth audience. E-cigarette advertisements contain messages that specifically appeal to youth with themes such as rebellion, freedom, rule-breaking, and independence (Figure 6).

This marketing increases the perception that e-cigarettes are socially acceptable, beneficial, and pose little risk to the consumer. With the integration of traditional marketing techniques into electronic and social media, these messages are increasingly effective at targeting youth and young adults as they appear to come from peers or celebrity figures, rather than the manufacturer or retailer.

E-cigarettes are promoted in the retail environment without restrictions. They are displayed on counters and by cash registers, often near candy and little cigars (Figure 7), which increases product awareness, provides easy access, and may decrease youth perceptions of risk and increase perceived benefits of e-cigarette use. (The FDA should also prohibit this placement for little cigars and other deemed tobacco products as well.)

The FDA should require that these products be placed behind the counter away from other products that would have youth appeal.

Youths can purchase e-cigarettes online

As the proposed deeming rule notes, “Electronic cigarettes (or e-cigarettes)... are widely available...on the Internet...” (p. 23146), and age limits are not enforced for online purchases of e-cigarettes.

¹⁴ USDHHS (2012). *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*

¹⁵ Grana R, Ling P (2014). Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*;46(4):395-403.

¹⁶ Andrade M, Hastings G, Angus K (2013). Promotion of electronic cigarettes: tobacco marketing reinvented? *BMJ*;347:f7473

¹⁷ American Legacy Foundation, (May 2014). *Vaporized: E-Cigarettes, Advertising, and Youth*. Available at: http://legacyforhealth.org/content/download/4542/63436/version/1/file/LEG-Vaporized-E-cig_Report-May2014.pdf

In a 2012 content analysis of e-cigarette retail websites, most sites did not have any age restriction to view or enter.¹⁸ For the small number of sites that did, users were usually instructed simply to “click here” if they were over 18, without any other verification.

Despite the age limit on purchasing regulated tobacco products, the 2012 National Youth Tobacco Survey (NYTS)¹⁹, in combination with current US population estimates,²⁰ revealed that approximately 85,000 adolescents in the US had purchased cigarettes; cigars, cigarillos, or little cigars; or chewing tobacco, snuff, or dip online in the past month.²¹ Unfortunately, the NYTS does not ask about online purchasing of e-cigarettes, but the similarity in marketing and distribution as other tobacco products suggests that youth have similar access to e-cigarettes.

E-cigarettes are advertised as healthier than tobacco cigarettes, which also appeals to youth

E-cigarette companies are marketing e-cigarettes as healthier alternatives to cigarette smoking (Figure 8).^{22,23,24,25} The smoking literature shows that adolescents who smoke or intend to start smoking anticipate lower risks and higher benefits of smoking than nonsmokers and adolescents who don't intend to smoke in the future.²⁶

For example, in a study of 1,226 male high school baseball players, the prevalence of smokeless tobacco use was higher among those who believed that smokeless tobacco was unlikely to pose personal health risks. Compared with players who believed personal risk was likely, the odds of current ST use were 3.6 for those who believed it was unlikely they would get mouth cancer, 4.2 for those who believed it was unlikely they would get a sore mouth or throat, and 3.3 for those who believed it was unlikely they would get gum disease.²⁷ In addition, “young adults often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes.” (p.23146) Furthermore, dual use of e-cigarettes and cigarettes is very high among middle and high school students.²⁸

¹⁸ Grana R, Ling P (2014). Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*;46(4):395-403.

¹⁹ Centers for Disease Control and Prevention. National Youth Tobacco Survey. Available at: http://www.cdc.gov/TOBACCO/data_statistics/surveys/NYTS/index.htm. Accessed May 16, 2014.

²⁰ ²⁰ US Census Bureau. American Community Survey. Available at: http://www.census.gov/acs/www/data_documentation/public_use_microdata_sample/. Accessed May 16, 2014.

²¹ Rebecca Williams (2014). Personal correspondence. May 14, 2014.

²² Lee et al (2011). Public Health Challenges of Electronic Cigarettes in South Korea. *Journal of Preventive Medicine and Public Health*, 44: 235-241.

²³ de Andrade and Hastings (2013). The Marketing of E-Cigarettes: A UK Snapshot *BMJ Group Blogs* <http://blogs.bmj.com/tc/2013/04/06/the-marketing-of-e-cigarettes-a-uk-snapshot/>. Accessed April 16, 2013.

²⁴ Yamin et al, (2010). E-Cigarettes: A Rapidly Growing Internet Phenomenon. *Annals of Internal Medicine*, 153: 607-609.

²⁵ Grana & Ling, (2014). Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*, 46 (4): 395-403.

²⁶ Halpern-Felsher BL, Biehl M, Kropp RY, Rubinstein ML (2004). Perceived risks and benefits of smoking: differences among adolescents with different smoking experiences and intentions. *Preventive Medicine*;39(3):559-567.

²⁷ Walsh M, Ellison J, Hilton JF, Chesney M, Ernster VL (2000). Spit (smokeless) tobacco use by high school baseball athletes in California. *Tobacco Control* 9(Suppl II) ii32-ii39.

²⁸ Dutra and Glantz (2014). Electronic cigarettes and conventional cigarette use among US adolescents a cross-sectional study. *JAMA Pediatrics*. Epub ahead of print.

E-cigarettes are promoted as approved by FDA

The Family Smoking Prevention and Tobacco Control Act explicitly prohibits use of “FDA-approved” language for marketing of tobacco products, but this restriction currently does not apply to e-cigarettes, which are sometimes advertised as “made in an FDA-approved facility”.^{29,30,31} Some e-cigarette products explicitly bear the FDA label (Figure 9). The same restriction as in the Section 103 (tt) of FSPTCA³² should be applied to the products covered in the deeming rule.

Overall Conclusions

E-cigarettes are advertised with unsubstantiated claims and in many ways that appeal to youth. The FSPTCA and the Master Settlement Agreement already prohibit many of these exploitive techniques, and FDA should use its authority under the FSPTCA to extend the prohibitions to e-cigarettes and all newly covered products.³³ The FDA has the authority under sections 906(d) and 907 of the Family Smoking Prevention Tobacco Control Act³⁴ to issue regulations requiring restrictions on the sale and distribution of tobacco products for the protection of the public health.

The FDA should take the following actions as a result of the information in this comment:

1. Ban e-cigarette advertising on television, radio, and electronic media.
2. Ban e-cigarette marketing at events (all events open to youth under age 18), magazines, and other media (media with a 10% or higher youth readership).³¹
3. Ban all e-cigarette flavors.
4. Stop allowing e-cigarette manufacturers to make indirect health claims.
5. Ban explicit or implicit statements that e-cigarettes are approved or endorsed by the FDA.
6. Prohibit product placement in movies unless R rated.
7. Prohibit sports sponsorship or advertising at sports events attended by youth under age 18.
8. Apply all of the same advertising restrictions to e-cigarettes that are already in place for cigarettes, including TV, radio, billboards, venues, etc.

²⁹ Paradise Vape. <http://www.paradisevape.net/about-us.html>

³⁰ 21st Century Smoke. <http://www.21stcenturysmoke.com/product-p/37-515cr.htm>

³¹ Q Vapor Labs inc. <http://qvapour.com/legal-compliance/?age-verified=d7962e9784>

³² Section 103 of the Tobacco Control Act- Conforming and Other Amendments to General Provisions, (May 2014). Available at: <http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm261876.htm>

³³ Master Settlement Agreement, (May 2014). Available at: <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement>

³⁴ Pub.L. 111-31, H.R. 1256 (June 22, 2009)



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Figure 1: Flavors of e-cigarettes Sources: www.blucigs.com and www.vaporcouture.com. Accessed: May 2013



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Figure 2: E-cigarette advertisement in Sports Illustrated magazine March 2014. Source: <http://www.npr.org/2014/03/03/284006424/e-cigarette-critics-worry-new-ads-will-make-vaping-cool-for-kids>. Accessed May 2014.



Figure 3: Blu advertisement. Source: www.blucigs.com. Accessed September 2013

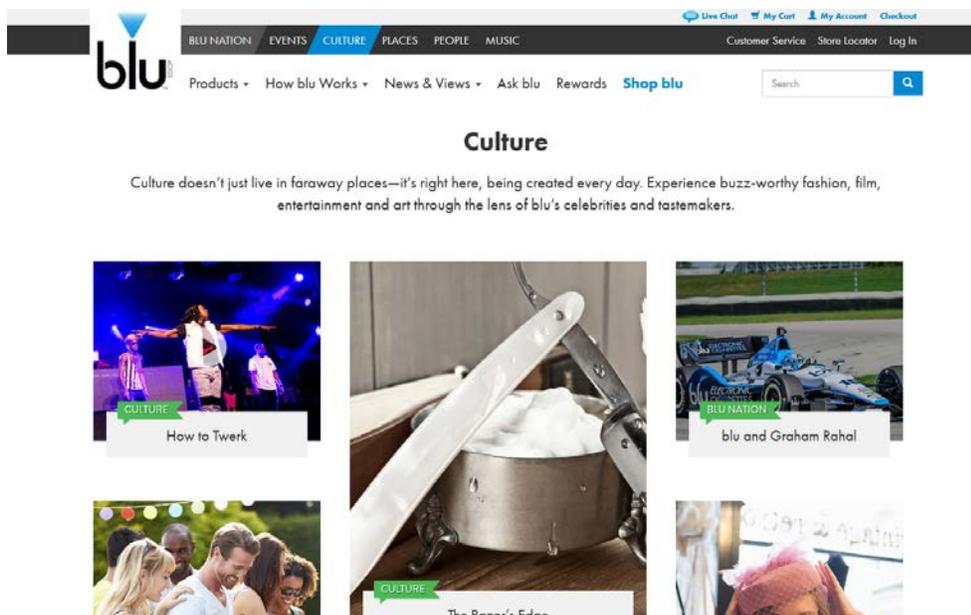
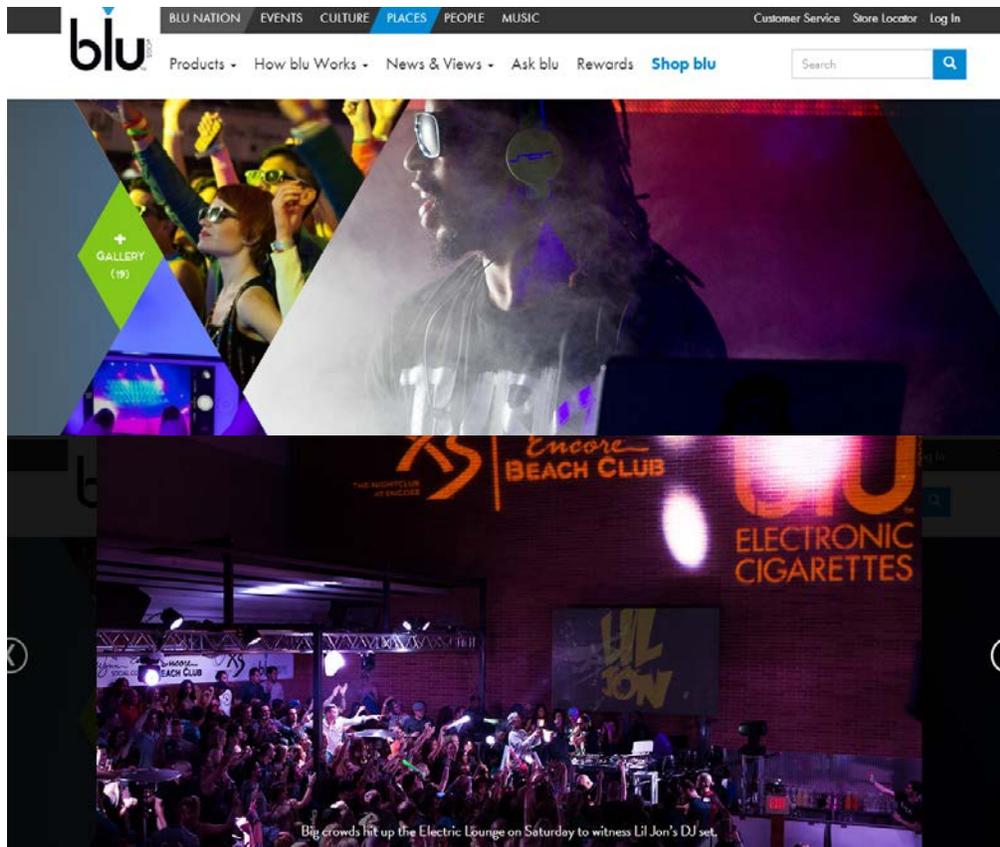


Figure 4: Blu e-cigarettes website pages featuring images from their sponsored events. **Top:** “electric lounge” at SXSW music festival in Texas. <http://www.blucigs.com/blu-events/> Accessed April 2014. **Bottom:** Featured aspects of youth and young adult culture and behavior such as "twerking," NASCAR sports sponsorship and parties and fashion <http://www.blucigs.com/blu-nation/culture/> Accessed May 2014



A screenshot of the NJOY website. At the top left is the logo for "WHERE™ ELECTRONIC CIGARETTES". To the right are navigation links: "My Account", "My Wishlist", "My Cart", "Checkout", "Log In", and "Store Locator". Further right are social media links: "Like 2.8k", "Pin it", and "Follow @ne_where 3,186 followers". Below these are three promotional boxes: "FREE SHIPPING", "30 DAY MONEY BACK", and "ONE YEAR WARRANTY". A dark navigation bar contains links: "Buy Online", "How It Works", "Partners", "Find a Store", "News & Events", and "Support". The main banner features the text "8 UNIQUE FLAVORS E-HOOKAH" above eight e-hookah pens, each with a different flavor and corresponding fruit/ingredient image. A "BUY NOW" button is centered below the pens. At the bottom, a "GET SOCIAL!" section encourages users to post pictures using #NEWHERE and tag the brand on Facebook, Instagram, and Twitter.

Figure 5: Promoting e-cigarettes through social media. **Top:** NJOY website accessed September 2013. **Bottom:** Source: <http://newhere.com/e-hookah-pen>. Accessed May 2014

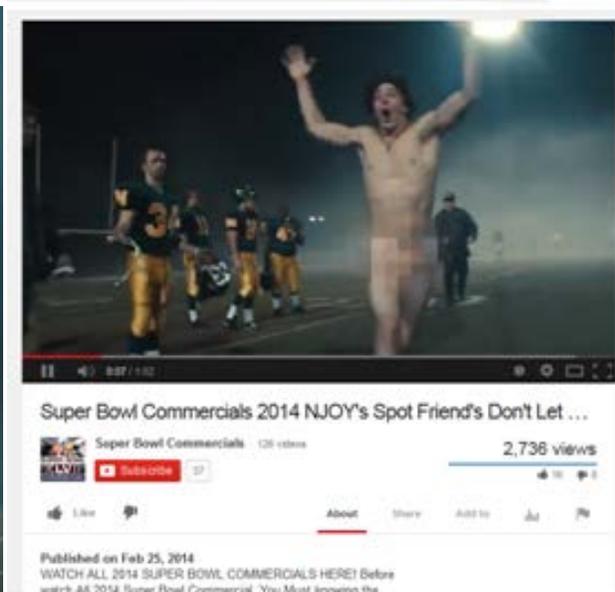


Figure 6: E-cigarette advertisements emphasizing rule-breaking, autonomy and independence. **Top:** Blu e-cigarettes magazine advertisement, Source: <http://tobacco.stanford.edu/> Accessed May 2014. **Middle:** Source: <http://tobacco.stanford.edu/> Accessed May 2014. **Bottom two images:** NJoy TV Commercial. www.youtube.com/njoy Accessed May 2014



Figure 7: Top: NJOY e-cigarette carousel next to a Mentos candy carousel on a counter in a convenience store in Missoula, Montana. Source: Anna Kostygina, August 2013. **Bottom:** Photo of Krave e-cigarettes and swisher little cigars on counter. Source: www.countertobacco.org Accessed May 2014



Figure 8: Top: Egar Electronic Cigarettes Website promotes e-cigarettes as a healthier alternative to smoking. <http://www.egar.com.au/>. Accessed June 2014. **Bottom:** South Beach Smoke Electronic Cigarettes ad promotes e-cigarettes as a part of a healthier lifestyle. <http://www.policymic.com/articles/89617/the-bad-news-keeps-coming-for-people-who-smoke-e-cigarettes>. Accessed June 2014.



Figure 9. E-cigarette liquid refill bearing the FDA label. <http://www.fasttech.com> Accessed May 2014