# LETTERS TO THE EDITOR

To the Editor:

The article by Bryan A. Liang "Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales"<sup>1</sup> (the "AJLM article") contains many inaccuracies and notable omissions. It could easily mislead a reader to believe that an American purchasing a drug from a pharmacy anywhere in the world other than the United States represents a grave safety issue, which is not true. Similarly it misrepresents the safety of purchasing medication from online pharmacies that have been carefully verified in the PharmacyChecker.com program, which the article grossly mischaracterizes.

One glaring omission from the author's own byline is his role as Vice President and Director of the pharmaceutical-sponsored Partnership for Safe Medicines which, not surprisingly, actively opposes all personal drug importation. Soon after publication, the AJLM article was posted for public access on this group's website, using the *AJLM* imprimatur to validate and broadcast its misleading statements.

The article describes the role of U.S. Customs to include "prohibiting individuals other than the original manufacturers from re-importing drugs back into the U.S." but there is no mention of the highly relevant FDA policy of permitting personal importation of up to a 90-day supply of a medication.

The article asserts that PharmacyChecker.com "permits the dangerous practice of online drug sellers simply using an 'online consultation' as the basis for prescription sales." A single pharmacy is offered to support this claim but the article fails mention that 1) the State of Utah has expressly permitted this particular pharmacy to use a sophisticated online medical consultation process to provide only five non-narcotic medications and 2) the PharmacyChecker.com program prohibits the use of online prescribing unless expressly permitted by law, as in this rare case.

The author also claims that, "Verified' pharmacies sell fake drugs and do not fulfill the supposed 'requirements'." To support this outrageous claim, the article states that an online pharmacy that "had been disciplined in 2001... for filing more than 10,000 medication orders from U.S. patients without a valid prescription ... continued to be a PharmacyChecker.com verified pharmacy..." This is impossible as PharmacyChecker.com did not begin verifications until 2003.

The article mentions the recent Ryan Haight Online Pharmacy Consumer Protection Act (which prevents the online sale of narcotics without a prescription based on a physical examination by a licensed doctor) but fails to note that 1) compliance is necessary for PharmacyChecker.com membership, and, furthermore, 2) PharmacyChecker.com prohibits membership to non-U.S. pharmacies that sell controlled substances into the U.S.

<sup>&</sup>lt;sup>1</sup> Bryan A. Liang, Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales, 35 Am. J. L. MED. 125 (2009).

These are just some of the many misrepresentations and inaccuracies of the article. In complete contrast to the article's assertions, online pharmacies that are verified by PharmacyChecker.com are rigorously monitored for compliance with strict standards. In addition, the leading search engines use these verifications to qualify pharmacy advertisers and help protect consumers (contrary to article's contention of a "lack of any oversight by search engines"). We suggest that AJLM more carefully verify the truthfulness and accuracy of its articles and require disclosure by its authors of relationships that are relevant to their subject matter.

Sincerely,

*Tod Cooperman, MD* President, PharmacyChecker.com

Gabriel Levitt Vice President, PharmacyChecker.com

#### SEARCHING FOR SAFETY: A REPLY TO COOPERMAN AND LEVITT

### To the Editor-in-Chief:

In a letter to the editor,<sup>1</sup> Tod Cooperman, MD, and Gabriel Levitt, President and Vice President of PharmacyChecker.com, contend that our piece, *Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales*,<sup>2</sup> "contains many inaccuracies and notable omissions."<sup>3</sup> We address each of their claims in turn.

### CLAIMS AND REPLIES

Cooperman and Levitt first state one "glaring omission" is Liang's affiliation with "the pharmaceutical-sponsored Partnership for Safe Medicines ["PSM"] which, not surprisingly, actively opposes all personal drug importation."<sup>4</sup> The clear implication is that Liang is trying to hide this affiliation, which somehow indicates our piece has an insidious agenda of fomenting resistance to importation.

First, Liang's PSM affiliation is well known. In numerous academic articles,<sup>5</sup> editorials,<sup>6</sup> and other media settings,<sup>7</sup> Liang is so identified. There is

<sup>&</sup>lt;sup>1</sup> Tod Cooperman & Gabriel Levitt, Letter to the Editor, supra.

<sup>&</sup>lt;sup>2</sup> Bryan A. Liang & Tim Mackey, Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales, 35 Am. J. LAW & MED. 125 (2009).

<sup>&</sup>lt;sup>3</sup> See Liang, supra note 1.

<sup>&</sup>lt;sup>4</sup> See id.

<sup>&</sup>lt;sup>5</sup> See, e.g., Bryan A. Liang, Pigs, Drugs and Terrorists, 5 PATIENT SAFTEY & QUALITY HEALTHCARE 10 (2008); Bryan A. Liang, A Dose of Reality: Promoting Access to Pharmaceuticals, 8 WAKE FOREST INTEL. PROP. L.J. 301 (2008) [hereinafter Dose]; Bryan A. Liang, Fade to Black: Importation and Counterfeit Drugs, 32 AM. J. LAW & MED. 279 (2006) [hereinafter Fade to Black]; Bryan A. Liang, Over the Virtual and Geographic Borders:

no effort to disguise this connection. Of course, Liang's PSM activities are also expressly indicated on its website in numerous places.<sup>8</sup>

Indeed, both of us strongly support PSM's activities to protect the safety of prescription drugs.<sup>9</sup> These include consumer drug safety checklists, counterfeit drug email alerts, low cost/no cost drug program information,<sup>10</sup> policymaker tools,<sup>11</sup> and professional resources.<sup>12</sup> The latter include an updated collection of published research relevant to the topic,<sup>13</sup> not merely our *American Journal of Law & Medicine* article "using the *AJLM* imprimatur to validate and broadcast... misleading statements."<sup>14</sup>

http://www.signonsandiego.com/uniontrib/20071221/news\_lz1e21liang.html.

<sup>8</sup> See, e.g., Partnership for Safe Medicines, Partnership for Safe Medicines Board of Directors, http://www.safemedicines.org/psmboard.html (last visited Sept. 10, 2009); Partnership for Safe Medicines, Bryan A. Liang, MD, PhD, JD, http://www.safemedicines.org/2007/11/bryan-a-liang-md-phd-jd.html (last visited Oct. 1, 2009); as well as numerous blog entries, see Partnership for Safe Medicines, http://www.safemedicines.org/bryan-a-liang-md-phd-jd/ (last visited Oct. 1, 2009).

<sup>9</sup> See Partnership for Safe Medicines, About Us,http://www.safemedicines.org/aboutpsm.html (last visited Oct. 3, 2009) [hereinafter Partnership for Safe Medicines].

<sup>12</sup> See Partnership for Safe Medicines, *LEADER's Guide for Pharmacists, available at* http://www.safemedicines.org/resources/PSM%20LEADERs%20Guide.pdf; Partnership for Safe Medicines, Simple Steps for SAFE Sourcing, http://www.safemedicines.org/safesourcing.html (last visited Oct. 3, 2009).

<sup>13</sup> See Partnership for Safe Medicines, *Peer Reviewed Articles*, http://www.safemedicines.org/peer-reviewed-articles/ (last visited Oct. 4, 2009).

<sup>4</sup> See Laing, supra note 1.

Understanding Importation and Counterfeit Drugs, 36 CAL. WEST. INT'L L.J. 7 (2005); Bryan A. Liang, Parallel Trade in Pharmaceuticals: Injecting the Counterfeit Element into the Public's Health, 31 N.C. J. INT'L L. COMM. REG. 847 (2006) [hereinafter Parallel Trade; and Bryan A. Liang, Regulating Follow-on Biologics, 44 HARV. J. LEGIS. 363 (2007); Bryan A. Liang, Structurally Sophisticated or Lamentably Limited? Mechanisms to Ensure Safety of the Medicine Supply, 16 ALB. L.J. SCI. & TECH. 483 (2006) [hereinafter Structurally Sophisticated].

<sup>&</sup>lt;sup>6</sup> See, e.g., Bryan A. Liang, How to Crack Down on Counterfeit Drugs from China, N.H. UNION LEADER, Mar. 14, 2008, available at http://www.unionleader.com/article.aspx?headline=Brian+Liang%3A+How+to+crack+down+ on+counterfeit+drugs+from+China&articleId=75f1146e-d577-489a-8edb-38a730f93887; Bryan A. Liang, Recognizing a prescription for disaster, STAR-TRIBUNE (VA), Sept. 29, 2008, available at http://www.wpcva.com/articles/2008/09/29/chatham/opinion/opinion09.txt, and Bryan A. Liang, A Very Real Drug Importation Threat, SAN DIEGO UNION TRIB., Dec. 21, 2007, available at

See, e.g., New Year, New President, New Packaging?, ePACKAGE NEWSLETTER, Jan. 6, 2009, available at http://www.devicelink.com/pmpn/newsletters/01\_06\_09.html (referring to Liang as "vice president, Partnership for Safe Medicines"); Elaine Kurtenbach, Companies Back A gainstChina July 2006, available Fight Piracy, 2,http://www.foxnews.com/wires/2006Jul02/0,4670,ChinaFightingFakes,00.html (last visited Oct. 3, 2009) (referring to Liang as "vice president, Partnership for Safe Medicines); Elaine Kurtenbach, Heparin Highlights Problems Regulating Global Drugs, MANUFACTURING.NET, Apr. 11, 2008, available at, http://www.manufacturing.net/News-Heparin-Highlights-Problems-Regulating-Global-Drugs.aspx?menuid=282 (referring to Liang as "an advisor to the Partnership for Safe Medicines").

<sup>&</sup>lt;sup>10</sup> See Partnership for Safe Medicines, Partnership for Safe Medicines Consumer Resources, http://www.safemedicines.org/consumer\_resources.html (last visited Oct. 3, 2009).

<sup>&</sup>lt;sup>11</sup> See Partnership for Safe Medicines, Counterfeit Drug Incident Encyclopedia, http://www.safemedicines.org/counterfeit-drug-incident-encyclopedia.html (last visited Oct. 3, 2009); Principles for Drug Safety, http://www.safemedicines.org/doctrine\_principles.html (last visited Oct. 3, 2009).

Further, PSM is not merely a "pharmaceutical-sponsored"<sup>15</sup> group. Stakeholders from a wide array of perspectives—academia, industry, professional associations, patient groups, and public health organizations are members and support its mission "to protect consumers from counterfeit or contraband medicines."<sup>16</sup> Members include University of Texas College of Pharmacy, Biotechnology Industry Organization, Pharmaceutical Research and Manufacturers of America, American Pharmacists Association, Interamerican College of Physicians & Surgeons, National Association of Boards of Pharmacy, National Alliance for Hispanic Health, Community AIDS National Network, and the World Health Organization, amongst others.<sup>17</sup>

In addition, Liang has been open in his resistance to proposed drug importation policy on practical,<sup>18</sup> technological,<sup>19</sup> and international law and enforcement grounds.<sup>20</sup> Liang has also written on the risk of importation policy failure falling upon vulnerable patient groups.<sup>21</sup> This perspective does not rely on any purportedly surreptitious association with PSM.

Cooperman and Levitt then indicate that in our discussion of US law prohibiting drug importation, we were lax (or worse) because "there is no mention of the highly relevant FDA policy of permitting personal importation of up to a 90-day supply of a medication."<sup>22</sup> However, their belief in some kind of FDA "personal importation" exception is patently incorrect. The relevant FDA policy in its *Regulatory Procedures Manual* states that personal importation may be allowed only:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or

2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.<sup>23</sup>

<sup>&</sup>lt;sup>15</sup> See id.

<sup>&</sup>lt;sup>16</sup> See Partnership for Safe Medicines, *supra* note 9.

<sup>&</sup>lt;sup>17</sup> See Partnership for Safe Medicines, Partnership for Safe Medicines Members, *available at* http://www.safemedicines.org/psm\_members.html (last visited Oct. 4, 2009).

<sup>&</sup>lt;sup>18</sup> See Fade to Black, supra note 4.

<sup>&</sup>lt;sup>19</sup> See Structurally Sophisticated, supra note 4.

<sup>&</sup>lt;sup>20</sup> See Parallel Trade, supra note 4.

<sup>&</sup>lt;sup>21</sup> See Dose, supra note 4.

 $<sup>^{\</sup>scriptscriptstyle 22} See$  Liang, supra note 1.

<sup>&</sup>lt;sup>23</sup> See Fade to Black, supra note 4 at 308 n.188 (quoting Office of Regulatory Affairs, U.S. Food and Drug Admin., Subpart Coverage of Pers. Importations in Regulatory Procedures Manual).

Clearly this policy is not a license for personal importation. Importantly, online drug purchasing does not fulfill the requirements of these provisions. Without doing so, as noted by the FDA, "virtually all prescription drugs imported for personal use into the United States . . . violate the [Federal Food, Drug, and Cosmetics Act] . . . [and] is prohibited under 21 U.S.C. §§ 331(d), and/or (a)."<sup>24</sup>

Cooperman and Levitt then criticize our observation that PharmacyChecker.com permits verified sites to use online consultations since we only mention "a single pharmacy", and that they prohibit the use of online prescribing unless "expressly permitted by law." The example we provide is KwikMed.com. Although they indicate that Utah permits such activities, Cooperman and Levitt ignore the fact that the Arkansas Attorney General is seeking enforcement penalties against KwikMed.com for violating its laws, as we note in our article.<sup>25</sup> Hence, according to the Arkansas Attorney General, KwikMed.com is violating state law in using online questionnaires, and such operations are not "expressly permitted by law" as claimed by Cooperman and Levitt.

Beyond the KwikMed.com illustration, it is not just "a single pharmacy" PharmacyChecker.com has verified that uses suspect online consultations. Many other verified sites also engage in this practice, contrary Cooperman and Levitt's claim.<sup>26</sup> But further, PharmacyChecker.com verified sites are activities. linked to additional. related unlawful For example. Shopeastwest.com, a PharmacyChecker.com verified online seller in India, "requires" a prescription or a "risk release form" in lieu of a prescription." Further, a link on its home page stating "can't find what you [sic] looking for click here" brings one to Superdrugsaver.com. This linked site sells controlled

<sup>&</sup>lt;sup>24</sup> See *id.* (quoting Letter from Randall W. Lutter, Ph.D., Assoc. Comm'r for Policy and Planning, U.S. Food and Drug Admin., to Governor Kenny Guinn, Governor of Nev. (May 20, 2005)).

<sup>&</sup>lt;sup>25</sup> See Liang & Mackey, supra note 2, at 139.

<sup>&</sup>lt;sup>26</sup> See, e.g., DoctorSolve.com, http://www.doctorsolve.com (last visited Sept. 5, 2009) (indicating "Your health profile is reviewed by our Canadian graduate nurses and pharmacy by technicians. All prescriptions are dispensed licensed pharmacists."); OnlicePharmaciescanada, http://www.onlinepharmaciescanada.com ("Upon ordering your discount canadian [sic] prescriptions your health profile is consulted with [sic] our Canadian graduate nurse or pharmacy technician and promptly filled by a licensed pharmacist."); SelfServeRX, http://www.selfserverx.com/viagra.asp ("Follow these simple steps to order: 1. Select a quantity from the list below. 2. Register if you are a new customer or log-in. 3. Complete the online consultation. 4. Checkout."). Further, in another interesting twist and illustration of PharmacyChecker.com verification process weakness, some verified online drug sellers are selling prescription drugs without a prescription by claiming that "Once a product has been classified as an OTC [over-the-counter] product in one developed country, it will inevitably become an OTC product in many other countries . . . . The reason you can buy the no prescription Flonase (Fluticasone Propionate) from MedStore International is because it is an OTC product in the country from where it is sourced." Medstoreinternational, Buy no prescription Flonase online,http://www.medstoreinternational.com/buy-Flonase.php (last visited Sept. 10, 2009) (emphasis supplied).

<sup>&</sup>lt;sup>27</sup> See ShopEastWest.com, New Patient Fax Order Form, available at, http://www.shopeastwest.com/med/Print%20and%20Order%20form.pdf (directing patient to "Attach Prescription Here or Fill Out the Risk Release Form", *id.* at 1, and "Incase [sic] No Prescription Is provided Please Also Fill the Risk Release Form and Fax Along with the Above Details", *id.* at 6).

substances, including narcotics,<sup>28</sup> without a prescription.<sup>29</sup> Shopeastwest.com and Superdrugsaver.com are apparently within the same affiliate network.<sup>30</sup> This result indicates that PharmacyChecker.com problems extend even further beyond allowing verified sites to use online consultations to sites using paper affirmations with sister sites selling controlled substances without a prescription.

In addition, we note that another PharmacyChecker.com verified online drug seller, Pharmnet.com, has dispensed entirely with even the online survey. Pharmnet.com was investigated by CNN, which found the site was simply selling controlled substances without a prescription.<sup>31</sup> Further, its products came from India, and package contents were fraudulently labeled as "documents."32 After the CNN story aired, Pharmnet.com was removed from the PharmacyChecker.com website,33 yet the online drug seller still advertises itself as (and presumably still is) a PharmacyChecker.com verified site.<sup>34</sup> Further, Pharmnet.com had applied for accreditation with LegitScript, and during this process disclosed that it held only a Texas license but was shipping to all 50 states, violating at least 45 state pharmacy practice laws.<sup>35</sup> This seller was rejected by LegitScript but still verified by PharmacyChecker.com.<sup>36</sup> Hence, KwikMed.com as well as other PharmacyChecker.com verified sites are in violation of the purported "expressly permitted by law" requirement, including violation of virtually all state pharmacy practice acts and selling controlled substances without a prescription.

<sup>28</sup> SuperDrugSaver.com, Pain Relief, See http://www.Superdrugsaver.com/category/7/Pain-Relief.html (last visited Sept. 5, 2009). Ironically, in its FAQs, the website indicates it does not sell controlled substances. See Superdrugsaver.com, FAQ: Do You Dispense Controlled Substances?, https://www.superdrugsaver.com/faq.php (last visited Sept. 6, 2009) (answer to this question is "No. We do not dispense any controlled substance.").

<sup>&</sup>lt;sup>29</sup> See SuperDrugSaver.com, FAQ: Do I require a prescription?, https://www.superdrugsaver.com/faq.php (last visited Sept. 6, 2009) ("We Prefer that you have a Valid Prescription by agreeing to the terms and conditions of the site you attest that you have a prescription or will obtain one by your physician in your country of residence, [sic] In order to fulfill your medical needs, our licensed physician upon request reviews each patient's medical history, and issues a prescription. Thus, for each order we can legally fill and ship your prescription in a discreet package that assures your confidentiality and privacy").

<sup>&</sup>lt;sup>30</sup> See SuperDrugSaver.com, Affiliate Program, http://www.superdrugsaver.com/affiliate/affsignup.php (last visited Sept. 6, 2009), cf. ShopEastWest.com, Affiliate Program, https://www.shopeastwest.com/med/affiliate/affiliatesignup.php (last visited Sept. 6, 2009).

<sup>&</sup>lt;sup>31</sup> See Illegal online pharmacies, CNN, Feb. 2, 2009, available at http://www.cnn.com/video/#/video/health/2009/02/02/dcl.giffin.online.drugs.cnn?iref=vide osearch; and LegitScript, CNN identifies PharmacyChecker-approved website linked to no-prescription-required Xanax, (Feb. 4, 2009), http://www.legitscript.com/blog/72.

<sup>&</sup>lt;sup>32</sup> See CNN, supra note 31.

<sup>&</sup>lt;sup>33</sup> See LegitScript, supra note 31.

<sup>&</sup>lt;sup>34</sup> See Pharmnet.com, About Our Pharmacy, http://www.pharmnet.com/pharmacy/aboutour-pharmacy.htm (last visited Sept. 5, 2009) ("PharmNet-Rx has been a member of pharmacy verification programs since they were established in 2003 . . . The Pharmacy Checker Seal indicates that a website markets prescription drugs dispensed from a pharmacy in good standing."). The CNN story aired Feb. 2, 2009, so at the time of this search, greater than six months had passed without action by PharmacyChecker.com to have, at a minimum, its logo removed from Pharmnet.com. Note that PharmacyChecker.com does not disclose all of its verified sites on its web page. See Liang & Mackey, *supra* note 2, at 139.

<sup>&</sup>lt;sup>35</sup> See LegitScript, supra note 31.

<sup>&</sup>lt;sup>36</sup> See LegitScript, *supra* note 31, and Pharmnet.com, *supra* note 34.

The letter then indicates that we were incorrect in our claim that PharmacyChecker.com does not ensure compliance of its requirements, pointing to our discussion of RxNorth.<sup>37</sup> However, they have misinterpreted our statement. PharmacyChecker.com verified RxNorth *despite the fact* that it had been disciplined for filling more than 10,000 medication orders from the US without a valid prescription.<sup>38</sup> Further, even during broad revelations in the media and Congress about RxNorth's operations,<sup>39</sup> PharmacyChecker.com continued RxNorth verification at the five checkmark, highest level status.<sup>40</sup> Our point is that PharmacyChecker.com continued with verification even in the face of documented violations of its own policy as well as during high profile investigations that also implicated violations of its requirements.

The letter then goes on to state that compliance with the Ryan Haight Online Pharmacy Consumer Protection Act ("Act") is mandated for PharmacyChecker.com membership, and non-US pharmacies are not permitted membership if they sell controlled substances.<sup>41</sup> First, we emphasize that unenforced "requirements" do little to ensure drug safety as we note in our article<sup>42</sup> and above. Indeed, we did find verified pharmacies that were selling controlled substances without a prescription.<sup>43</sup>

Second, Cooperman and Levitt's statement that "compliance is necessary" with the Act is curious. Their letter is dated May 4, 2009; interim final regulations were released April 6, 2009.<sup>44</sup> Hence, any compliance with the Act would necessarily rely on the terms of these regulations. Yet the PharmacyChecker.com website provides no information on the specific requirements for adoption by online drug sellers, nor is there any link to the regulations themselves, nor is there any means, mention, or explanation on how these requirements would be confirmed as fulfilled. Further, we note the absence of any PharmacyChecker.com comments on the interim rules,<sup>45</sup> which would not be expected by a corporate interest involved in substantively monitoring online sales, nor any recognition by Cooperman and Levitt that implementing regulations will be altered based on comments received after their letter was written.<sup>46</sup> Hence, "compliance" with the Act by

<sup>&</sup>lt;sup>37</sup> See Liang & Mackey, supra note 2, at 136.

<sup>&</sup>lt;sup>38</sup> See id. at 138.

<sup>&</sup>lt;sup>39</sup> See id. at 137 nn. 59-63 and accompanying text (discussing New York TIMES investigative series); id. at 137-138 nn. 52-58 and accompanying text (discussing Congressional hearings on counterfeits and online drug selling in RxNorth case).

<sup>&</sup>lt;sup>40</sup> See Liang & Mackey, supra note 37, at 138.

<sup>&</sup>lt;sup>41</sup> See Liang, supra note 1.

 $<sup>^{42}</sup>$  See Liang & Mackey, supra note 2, at 135-139 (outlining limited verification of online drug sellers).

<sup>&</sup>lt;sup>43</sup> See *id.* at 138 n.64 and accompanying text (noting LegalMedsDirect.com, a verified PharmacyChecker.com website, selling controlled substances such as Oxycodone, without a prescription).

<sup>&</sup>lt;sup>44</sup> See U.S. Department of Justice, Drug Enforcement Administration, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15596 (Apr. 6, 2009).

<sup>&</sup>lt;sup>45</sup> See Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Docket Folder, *available at* http://www.regulations.gov/search/Regs/home.html#docketDetail?R=DEA-2009-0004 (last visited Sept. 3, 2009).

<sup>&</sup>lt;sup>46</sup> Final regulations will take into account comments received up until June 5, 2009. *See* U.S. Department of Justice, *supra* note 44.

PharmacyChecker.com sites is questionable, since any terms of compliance with the interim regulations are not noted nor obviously available on its site, the company itself has not commented on implementation, and final regulations taking into account information received during the comment period are not yet available.

Finally, Cooperman and Levitt claim that "the leading search engines use [PharmacyChecker.com] verifications to qualify pharmacy advertisers and help protect consumers (contrary to the article's contention of a "lack of any oversight by search engines")."<sup>47</sup> First, we stand by our well-documented conclusions regarding lack of search engine oversight of online drug sales.<sup>48</sup> But further, we are not alone. In other recent reports, investigators analyzed Yahoo's and Microsoft's online drug advertising.<sup>40</sup> In contrast to Cooperman and Levitt's claim, and consistent with our conclusions, these investigations found that ~80-90% of reviewed search engine-sponsored online drug sellers do not require a prescription or are otherwise acting unlawfully or illegally.<sup>50</sup> This includes sales from India (a violation of search engine policy only allowing Canadian and US sellers), sales of counterfeit drugs, illegal sales of controlled substances, and sales by websites with organized crime connections.<sup>51</sup>

In addition, this state of affairs exists despite actual knowledge. Yahoo and Microsoft were notified of these issues by the National Association of Boards of Pharmacy in January 2008, National Center for Addiction and Substance Abuse in July 2008, and the American Pharmacists Association in February 2009.<sup>32</sup> Thus, the "rigorous[] monitor[ing] for compliance"<sup>53</sup> claimed by Cooperman and Levitt is belied by our work as well as other investigations.

One additional comment bears stating. The letter impugns the reputation of the editorial staff and the *American Journal of Law*  $\mathfrak{S}$  *Medicine* itself. With several hundred publications between us, we can state unequivocally that the AJLM staff were exemplary in their professionalism, activities, and assistance, and represent a model for all academic journals. They were our partners in the

<sup>&</sup>lt;sup>47</sup> See Liang, supra note 1.

<sup>&</sup>lt;sup>48</sup> See, e.g., Liang & Mackey, *supra* note 2 at 134-140.

<sup>&</sup>lt;sup>49</sup> See Legitscript & Knujon, No Prescription Required: Bing.Com Prescription DRUG ADS (2009), available at http://www.legitscript.com/BingRxReport.pdf [hereinafter NO PRESCRIPTION REQUIRED]; and LEGITSCRIPT & KNUJON, YAHOO INTERNET PHARMACY Advertisements: A Closer Look at Rogue Internet Pharmacies Sponsored by Yahoo's ONLINE Advertising Program (2009),available at: http://www.legitscript.com/YahooRxAnalysis.pdf [hereinafter YAHOO INTERNET PHARMACY ADVERTISEMENTS]: see also Arch G. Mainous et al., Availability of Antibiotics for Purchase Without a Prescription on the Internet, 7 ANN. FAM. MED. 431 (2009) (finding antibiotics available on Internet without prescription creating significant public health concern); and Grazia Orizio et al., Cyberdrugs: a cross-sectional study of online pharmacies characteristics, 19 EUR. J. PUB. HEALTH 375 (2009) (reporting 81.4% online pharmacies found using Google searches did not require prescription from a physician).

 $<sup>^{50}</sup>$  See No Prescription Required, supra note 49, at 3; Yahoo Internet Pharmacy Advertisements, supra note 49, at 3.

<sup>&</sup>lt;sup>51</sup> See No Prescription Required, *supra* note 49, at 3; and Yahoo Internet Pharmacy Advertisements, *supra* note 49, at 3, 30, 37.

<sup>&</sup>lt;sup>52</sup> See NO PRESCRIPTION REQUIRED, *supra* note 49, at 5; YAHOO INTERNET PHARMACY ADVERTISEMENTS, *supra* note49, at 41.

<sup>&</sup>lt;sup>53</sup> See Liang, supra note 1.

publication process and instrumental in ensuring that we were complete, comprehensive, and accurate in our use and citation of references. Their substantive suggestions as to the article's content were uniquely beneficial. Of course, any errors or omissions remain with us.

## CONCLUSION

Our paper, Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales, does not misrepresent nor does it contain inaccuracies claimed by Cooperman and Levitt. Indeed, misrepresentation and inaccuracies are extant in virtually all the claims made by these representatives of PharmacyChecker.com.

However, hurling vituperative epithets is counterproductive in efforts to ensure safety of the drug supply. Stakeholders must work together to craft systems that are resilient to the creativity of those who would cheat the sick and vulnerable. A necessary condition for doing this is a recognition of reality: that the Internet, through search engines, allows for illicit online drug sales. We must join together, face this reality, and with complete and accurate empirical, policy, and legal information, act to address this critical public health concern. Our article has hopefully contributed to that effort. We will continue to work responsibly to reach the goal that "no one must ever bet his or her life on the legitimacy of an online drug seller.".

Bryan A. Liang<sup> $\dagger$ </sup>  $\mathfrak{S}$  Tim Mackey<sup> $\dagger \dagger$ </sup>

<sup>&</sup>lt;sup>54</sup> See Liang & Mackey, supra note 2, at 175.

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## APROPOS "NEW VACCINES FOR DEVELOPING COUNTRIES: WILL IT BE FEAST OR FAMINE?

#### To the Editor:

We agree with Andrus et al<sup>1</sup> for innovative financial mechanisms to finance vaccines for human papilliomavirus infection, rotavirus and pneumococcal disease in Latin America and the Caribbean. Involvement of masses along with linkage of such vaccinations to important individual events and/or other occasions for celebrations should emerge as an alternative.

For infants and young children, such immunization could be linked to the birthday of the individual. Parents or close relatives and family friends could be encouraged to consider such immunizations as an important birthday gift for their children. Moreover, elderly with grandchildren could be reciprocated with vaccine shots as an annual gift. Parents' day, mother's day or the celebration of a wedding anniversary such as a golden or diamond jubilee would be ideal. Events such as Christmas and New Year's Day do imply a festive atmosphere in Latin American countries and the Caribbean. Local supermarkets offer several incentives to customers to purchase gifts. There is often a discount on innumerable items for the customers. During such events, manufacturers of vaccines for human papilliomavirus infection, rotavirus and pneumococcal disease could plan innovative strategies intended to increase sale of these products. Attractive discounts could be offered to stimulate masses to receive annual dose of different vaccines.

Last but not least, any fiscal input from the local community in Latin America and the Caribbean region would orchestrate future input to the PAHO revolving Fund for new generation of vaccines.<sup>2</sup>

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<sup>&</sup>lt;sup>1</sup> Jon Kim Andrus et al., New Vaccines for Developing Countries: Will it be Feast or Famine?, 35 Am. J.L. & MED. 311 (2009). <sup>2</sup> Id.