

**VIA Electronic Submission to <http://www.regulations.gov>**

June 5, 2009

Drug Enforcement Administration  
Attention: DEA Federal Register Representative/ODL  
8701 Morrissette Drive  
Springfield, VA 22152

*Re: Docket No. DEA-322: Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008; Interim Final Rule with request for comments; DEA-322; RIN 1117-AB20*

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the above-referenced interim final rule. The DEA has invited public comment, even though implementation of the rule began on April 13, 2009.

NCPA represents America's independent community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they employ over 300,000 full-time employees, and dispense nearly half of the nation's retail prescription medicines.

Independent community pharmacists are concentrated in both the most remote rural and the most densely-populated urban neighborhoods, and pride themselves on providing in-person care to their patients. Almost by definition, therefore, very few independent community pharmacies have to even consider whether they meet the definition of "online pharmacy" and its corresponding requirements under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Act") and the interim final rule. Those pharmacies that meet such definitions would have to obtain modification of registration from DEA for all post-April 13, 2009, internet business. Indeed, in his presentation on May 12, 2009, to NCPA's 41<sup>st</sup> annual Legislative and Government Affairs Conference, Mark Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, indicated that only several pharmacies have made such applications.

Despite such a small number of independent community pharmacies that are directly impacted by this registration requirement, NCPA expresses its support for the Act and for the general provisions of the interim final rule. As DEA aptly states, "online pharmacy" includes, among others, those persons who operate the types of rogue Web sites that the Act was designed to eliminate."<sup>1</sup> Rogue, illegitimate drug trafficking operations are anathemas to legitimate independent community pharmacies. They create among both the general public

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<sup>1</sup> 74 FR No. 64, April 6, 2009, at 15599.

and policymakers undeserved negative impressions of pharmacists and the valuable practice of pharmacy. NCPA supports efforts to control illegal distribution of controlled substances outside of the community pharmacy setting. More specifically, NCPA supports the Act's and the interim final rule's prohibition on all controlled substance activities by "online pharmacies" except those expressly authorized by the Act."<sup>2</sup>

In addition, we welcome DEA pointing out that a key exception to the modification of registration requirement is for those DEA-registered pharmacies "whose dispensing of controlled substances via the Internet consists solely of \* \* \*(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 802(55)] or (II) filling new prescription for controlled substances in schedule III, IV, or V, as defined in paragraph [21 U.S.C. 8082(56)]."<sup>3</sup> NCPA urges DEA to consistently emphasize this exception in communications regarding the DEA-322, the Act and their requirements.

NCPA's primary concern regarding DEA's enforcement of the Act and the interim final rule is whether DEA will truly follow the terms that it outlines in the preamble of DEA-322. DEA stated that there is no liability to pharmacists for failing to identify that a prescription from a practitioner was steered through an online pharmacy unless it should have reasonably suspected that such was the case through the exercise of proper professional practice or deliberately closed his eyes to circumstance indicative of a possible violation, and then the pharmacist failed to verify whether the prescription was "dispensed by means of the internet."<sup>4</sup> DEA also cites federal court standards of "deliberately clos[ing] his eyes to wrongdoing that should have been obvious to him", "willful blindness", "deliberate ignorance", and "burying ones head in the sand."<sup>5</sup> We urge DEA to apply such standards in the manner outlined in the preamble, as opposed to holding pharmacists to a more stringent standard that would extend beyond the care required to responsibly carry out the practice of pharmacy.

NCPA appreciates the opportunity to comment on the additions to 21 CFR Parts 1300, 1301, 1304, et al. If you have any questions, please contact me at (703) 683-8200 or [john.coster@ncpanet.org](mailto:john.coster@ncpanet.org).

Sincerely,



John M. Coster, Ph.D., R.Ph.  
Senior Vice President, Government Affairs  
National Community Pharmacists Association

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 15606.

<sup>4</sup> *Id.* at 15607.

<sup>5</sup> *Id.* at 15606.