

Comments Submitted to FDA 2010-N-0184

Experimental Study of Patient Information Prototypes

July 6, 2010

The National Community Pharmacists Association (NCPA) is pleased to offer comments on the proposed collection of information for research entitled “Experimental Study of Patient Information Prototypes”. NCPA represents the pharmacists and owners of more than 22,700 independent community pharmacies, pharmacy franchises, and chains. Together they represent an \$88 billion health-care marketplace, employ over 65,000 pharmacists and dispense over 40% of all retail prescriptions.

NCPA is strong advocate for the “one-document solution”

NCPA applauds the FDA’s position that consumers need access to up-to-date and accurate information about the risks, benefits and safe use of their prescription drugs in order to use their medications correctly and make informed decisions about their care. NCPA also applauds the recognition that consumers currently receive multiple pieces of paper from the pharmacy with their prescription drugs, containing information that is developed and distributed through various sources, which in some cases is difficult to read and understand and may be duplicative, incomplete and/or contradictory.

Our association has been active in offering feedback and support to the FDA in the creation and use of a single, FDA-approved plain language document to replace existing written information distributed by pharmacies. Recently, this feedback has included a presentation to the FDA Risk Communication Advisory Committee; participation in a FDA public workshop to discuss desirable features of a single-document leaflet; and submission of comment letters related to evaluation of consumer medication information and providing effective information to consumers about prescription drug risks and benefits.

NCPA supports content and format of the “one-document” based on consumer testing

NCPA acknowledges the value of, and supports the FDA, in collecting data used to create an effective single-page document which is formatted and contains content written to be most easily comprehended by consumers. NCPA would like to reemphasize our position on the importance of adopting a “one-document solution” in accordance with our previous comments as well as the citizen’s petition filed in 2008 which urges the FDA to issue guidance towards this end.

As strong advocates of the creation and use of an FDA-approved document which would be universally used and distributed in pharmacies, NCPA urges the use of technology already in place. Pharmacies should be able to work with their pharmacy management system vendors to access and print the document on demand, which in most cases would be a single sheet of paper that is easy to read and understand, is complete and concise, and contains embedded access to more detailed information for the patient if they desire. Use of the document will streamline and reduce costs to pharmacies as well as enhance the level of care to consumers. Today’s system is growing increasingly unworkable in the face

of Medication Guides being required for an increasing number of medications, far from the Medication Guide final rule FDA published in 1998.

In conclusion, NCPA contends that the proposed collection of information will have practical utility and encourages that the Agency be approved to launch this consumer study immediately.

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