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January 7, 2015

UnitedHealth Group
P.O. Box 1459
Minneapolis, MN 55440-1459

Dear UnitedHealth Group:

I am writing to inquire about the steps your pharmacy has taken to adopt recommended best practices to improve the accessibility of prescription drug label information to customers who are blind, visually-impaired, or elderly with deteriorating vision. As you know, in July 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which included a provision I developed that has established voluntary labeling and accessibility measures for adoption by pharmacies that will help make prescription drugs safer for individuals who are visually-impaired.[1,2] As required by the law, the Government Accountability Office (GAO) will soon begin to formally evaluate the extent to which pharmacies have complied with these recommended best practices to protect the safety and well-being of visually impaired patients and will report these findings to Congress.

Prescription drug labels provide consumers with vital information, including instructions for appropriate dosage, administration, storage, and disposal as well as warnings for interactions and potential side effects. Ensuring access to this information is important for the safety and well-being of all patients; however, there are at least 20.6 million Americans who experience vision loss preventing them from reading important prescription drug label information independently.[3] The inability to easily access prescription label information puts these individuals at risk for taking the wrong medicines or the wrong doses and impairs their ability to independently manage their prescription health needs.[4] Because many individuals experience deteriorating vision during the aging process and our nation's population is aging rapidly,[5] an inability to read prescription drug label information and the safety problems associated with this, is predicted to become a growing problem.[6]

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[1] H.R.4087 Prescription Drug Labeling Promotion Act of 2012
[2] P.L.112-144, 126 Stat. 993
[3] Statistical Snapshots from the American Foundation for the Blind. Available at http://www.afb.org/info/living-with-vision-loss/blindness-statistics/12 (citing the 2012 National Health Information Survey Preliminary Report. 2012 NHIS data available at http://www.cdc.gov/nchs/data/series/sr_10/sr10_260.pdf)
[4] American Council of the Blind. ACB Lauds U.S. Congress for Including Accessible Prescription Drug Labeling Language in FDA Bill That Now Moves to the President's Desk. June 26, 2012. Available at http://acb.org/node/942 See also Marek KD, Antle L. Medication Management of the Community-Dwelling Older Adult. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 18. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2670/
[5] Linda A. Jacobsen et al., "America's Aging Population," Population Bulletin 66, no. 1 (2011) Available at.http://www.prb.org/pdf11/aging-in-america.pdf
[6] American Council of the Blind. ACB Lauds U.S. Congress for Including Accessible Prescription Drug Labeling Language in FDA Bill That Now Moves to the President's Desk. June 26, 2012. Available at http://acb.org/node/942

Section 904 of FDASIA, intended to make compliance with the Americans with Disabilities Act[7] easier for pharmacies, authorized the United States Access Board (Board) to convene a working group to consider alternative or enhanced delivery methods (such as braille, large print, and audible devices) and to develop best practices for improving the accessibility of prescription drug label information.[8] In October 2012, the Board formed a working group composed of 18 members representing diverse stakeholders. Over the course of six meetings,[9] the working group developed best practice guidelines, which were published on July 10, 2013.[10] The FDASIA directed the Government Accountability Office (GAO) to conduct a study to determine the extent to which pharmacies have adopted practices consistent with the best practice guidelines and to report the study findings to Congress by September 30, 2016.[11]

As one of the largest pharmacies in the United States,[12] UnitedHealth Group is in an ideal position to improve access to drug safety information for many Americans. In anticipation of the GAO's upcoming investigation of pharmacy compliance with best practices for labeling for the visually impaired, I am contacting you to learn more about the measures your company has taken to make prescription drug label information more accessible to consumers who are blind, visually-impaired, or elderly with deteriorating vision. Please review the "Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly" online at http://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations and respond to the questions below by December 15, 2014:

1. Has your pharmacy adopted the "Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly"?
    a. If so, when did your pharmacy formally adopt these best practices?
    b. If not, does your pharmacy anticipate adoption these practices in the future? If so, when?
    c. If your pharmacy has not adopted these best practices and does not plan to do so in the future, why not?
    d. If your pharmacy has not adopted these best practices and does not plan to do so in the future, does your pharmacy follow alternative recommendations or guidelines that benefit accessibility for those who are visually impaired? If so, please describe these actions and how they compare to the best practices.

2. What specific measures has your pharmacy taken to improve access to prescription drug label information for those consumers who are blind, visually-impaired, or elderly with deteriorating vision?
    a. Do you offer consumers hard copies of the information in braille format?
    b. Do you offer consumers hard copies of the information in large print?
    c. Do you offer consumers special audible devices to deliver the information?

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[7] Pub. L. 101-336, 104 Stat. 327, enacted July 26, 1990, codified at 42 U.S.C. §12101 et. seq.

[8] Section 904 - Accessibility of information on prescription drug container labels by visually impaired and blind consumers.

[9] An in-person meeting was convened in Washington, DC on January 10-11, 2013 and five teleconference meetings were subsequently held.

[10] http://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations?highlight=WyJkcnVnIiwibGFiZWxzIiwiZHJ1ZyBsYWJlbHMiXQ==

[11] P.L.112-144, 126 Stat. 993, Sec. 904 (b)(2)

[12] http://www.drugchannelsinstitute.com/files/Largest_US_Pharmacies_Ranked_by_Total_Prescription_Revenues_2013.pdf (listing UnitedHealth Group as having the eighth highest estimated 2013 prescription revenues)

d. How do you inform consumers about the options available at your pharmacy to assist them in independently accessing drug label information? For example, do you specifically promote these options proactively or are options only available if consumers inquire or request them?
e. Please describe any other measures your pharmacy takes to ensure access.

3. Are the specific measures your pharmacy has taken to improve access to prescription drug label information for those consumers who are blind, visually-impaired, or elderly with deteriorating vision made available to consumers for free? If not, what fees are charged?

I appreciate your attention to this important matter. Please provide your response by January 27, 2015. If you have questions about this letter, please contact Dr. Jennifer Wagner or Dr. Avenel Joseph in my office at 202-224-2742.

Sincerely,

Edward J. Markey

Edward J. Markey
United States Senator