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January 22, 2015

The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

The Honorable Margaret Hamburg  
Commissioner  
Food and Drug Administration  
Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Administrator Tavenner and Commissioner Hamburg:

On behalf of AARP's nearly 38 million members, their families, and all Americans who depend on nursing facility services, I am writing to express AARP's concern about the excessive and inappropriate use of antipsychotic drugs in nursing facilities throughout the country. AARP encourages the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) to take additional steps to further increase awareness about the inappropriate use of antipsychotic drugs and protect nursing home residents with dementia who may be at risk.

We are pleased some progress has been made through CMS' National Partnership to Improve Dementia Care in Nursing Homes. In particular, we are encouraged by the Partnership's work in reducing the national prevalence of antipsychotic use in long-stay nursing facility residents by 15.1 percent. However, clearly more must be done to address this serious problem. Therefore, we are glad to see the Partnership's new goal to reduce the use of antipsychotic medications by 25 percent in long-stay nursing facility residents by the end of 2015, and 30 percent by the end of 2016. Given the potentially life-threatening risk of the use of these drugs, AARP urges CMS and FDA to undertake an expanded education campaign about the danger of these drugs and the importance of informed consent for all people in nursing facilities.

Over the past several months, many family members and caregivers of nursing facility residents contacted AARP for assistance after reading a July 2014 *AARP Bulletin* article entitled, “Drug Abuse: Antipsychotic Drugs in Nursing Homes.”<sup>1</sup> As this article describes, as many as 1 in 5 residents in the nation's 15,500 nursing homes are given antipsychotic drugs that are not only unnecessary, but extremely dangerous for older individuals. These drugs often are administered without informed consent. The problem, experts say, stems from inadequate training and chronic understaffing in the nursing facilities, as well as an aggressive push by pharmaceutical companies to market their products.

“Raising Expectations: A Scorecard on Long-Term Services and Supports for Older Adults, People with Physical Disabilities, and Family Caregivers” -- released by AARP, the Commonwealth Fund, and the SCAN Foundation last year -- includes an indicator regarding the percentage of long-stay nursing home residents who are receiving an antipsychotic medication. These data can be used by states to see how they compare to other states and to work toward improvement in this area.

AARP has previously urged CMS and FDA, as well as policymakers in Congress, to address the inappropriate use of antipsychotic drugs in nursing facilities. AARP Foundation Litigation has served as co-counsel in the case *Kathi Levine vs. Ventura Convalescent Hospital* that led to an unprecedented class-action suit against a nursing facility for administering antipsychotic drugs without the informed consent of residents or family members. AARP Foundation Litigation also recently filed a lawsuit against Life Care Greenville and Life Centers of America for administering antipsychotic drugs without informed consent. As noted in the link to the AARP Bulletin article above, AARP has also provided information for consumers and their families about what caregivers need to know about the use of antipsychotic drugs in nursing homes and about monitoring medications for nursing home residents.

Based on the response to the article and inquiries received from other families similarly affected, AARP requests that CMS and FDA undertake an enhanced, multi-pronged, effort to educate the public, nursing facilities, and physicians about the human consequence of misusing antipsychotic drugs, particularly for individuals who suffer from dementia and dementia-like symptoms.

- First, AARP encourages FDA and CMS to initiate a national discussion about the critical role of informed consent in providing requisite information to nursing facility residents and their families, agents, and caregivers, thereby allowing them to make informed decisions about the resident’s care and treatment options. CMS could also develop standardized informed consent protocols that could be used prior to prescribing antipsychotic drugs to residents.
- Second, AARP calls for an enhanced public education campaign identifying the drugs that carry a FDA black box warning and explaining what a black box

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<sup>1</sup> The article is available here: <http://www.aarp.org/health/drugs-supplements/info-2014/antipsychotics-overprescribed.html>.

warning is so that people can make informed decisions about the medications that are recommended for them or their vulnerable family member.

- Third, AARP requests that FDA and CMS examine the role that pharmaceutical companies play in advocating for the use of these drugs with nursing facility residents.
- Finally, CMS must continue and strengthen its efforts to decrease utilization of unnecessary drugs, including through oversight and enforcement measures. For at least some of the above items, CMS can build from its existing efforts and try to leverage existing tools and distribution channels, such as Nursing Home Compare, the aging network, and others.

Attached is a chart that details some examples of the public response to the *AARP Bulletin* article. AARP Foundation Litigation staff made personal contact with each individual noted to discuss their situation. To the extent that we have the information, we have provided the names of the drugs, the consequences for the victims who were administered the drugs, and the state in which the drugs were administered. Because such stories are not easily gathered, we are sharing them with you to enhance your public education efforts and understanding of the magnitude of the problem. Many of the people that we were in contact with want to share more detailed information if it would help to prevent the recurrence of these tragic outcomes for others. If your efforts would be assisted by more detailed information, please let us know and we will reach out to the people who contacted us to secure their consent to share in more detail the information they reported to us.

Thank you for your attention to this important issue. If you have any questions, please feel free to contact me, or please contact Rhonda Richards (rrichards@aarp.org) or KJ Hertz (khertz@aarp.org) on our Government Affairs staff at 202-434-3770. We look forward to hearing from you and working with CMS and FDA to improve the lives of older adults and their families.

Sincerely,



David Certner  
Legislative Counsel and Legislative Policy Director  
Government Affairs

Attachment – Chart Detailing Nursing Facility Events