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Kohl, Grassley and Blumenthal Seek to Cut Misuse of Antipsychotics

WASHINGTON – U.S. Senators Herb Kohl, D-Wis., Chuck Grassley, R-Iowa, and Richard Blumenthal, D-Conn., today filed an amendment seeking to combat the costly, widespread and inappropriate use of antipsychotics in nursing homes.

“The overuse of antipsychotics is a common and well-recognized problem that puts frail elders at risk and costs taxpayers hundreds of millions of dollars each year,” Kohl said. “We need a new policy that helps to ensure that these drugs are being appropriately used to treat people with mental illnesses, not used to curb behavioral symptoms of Alzheimer’s or other dementias.”

“This amendment responds to alarming reports about the use of antipsychotic drugs with nursing home residents,” Grassley said. “It’s intended to empower these residents and their loved ones in the decisions about the drugs prescribed for them.”

“This measure is responsive to mounting evidence that antipsychotics are being misused and overused in the nursing homes we trust to care for our loved ones,” Blumenthal said. “The amendment will do what is necessary to curb this deeply concerning practice, putting the power to make key health care decisions back into the appropriate hands and eliminating unnecessary costs to taxpayers.”

The [amendment](#) to S. 3187, the Food and Drug Administration Safety and Innovation Act would require the Health and Human Services Secretary to issue standardized protocols for obtaining informed consent, or authorization from patients or their designated health care agents or legal representatives, acknowledging possible risks and side effects associated with the antipsychotic, as well as alternative treatment options, before administering the drug for off-label use.

While the Food and Drug Administration (FDA) has approved antipsychotic drugs to treat an array of psychiatric conditions, numerous studies conducted during the last decade have concluded that these medications can be harmful when used by frail elders with dementia who do not have a diagnosis of serious mental illness. In fact, the FDA issued two “black box” warnings citing increased risk of death when these drugs are used to treat elderly patients with dementia.

Last year, the Health and Human Services Office of the Inspector General (HHS OIG) issued a report showing that over a six-month period, 305,000, or 14 percent, of the nation’s 2.1 million elderly nursing home residents had at least one Medicare or Medicaid claim for atypical antipsychotics.

The HHS OIG also found that 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions and that 88 percent were associated with a condition specified in the FDA box warning. Further, it showed that more than half of the 1.4 million claims for atypical antipsychotic drugs, totaling \$116.5 million, failed to comply with Medicare reimbursement criteria.

The amendment also calls for a new prescriber education program to promote high-quality, evidence-based treatments, including non-pharmacological interventions. The prescriber education programs would be funded through settlements, penalties and damages recovered in cases related to off-label marketing of prescription drugs.