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Senate of Pennsylvania

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FEB 01 2012

TO: ALL SENATORS

FROM: Senator Patricia H. Vance

DATE: January 31, 2012

SUBJECT: Memo #31–Legislation amending the Generic Equivalent Drug Law

In the near future, I will be introducing legislation to amend the Generic Equivalent Drug Law regarding biosimilar products.

Generic drugs and biosimilar medications have very different chemical make-ups. As a result, the laws currently applicable to generics cannot be applied uniformly to biosimilar products. Generic drugs have identical active substances as their brand counterparts while biosimilars are only comparable and are not always "scientifically appropriate" for substitution.

Current Pennsylvania law permits the automatic substitution of a less expensive generic drug for a brand name drug unless the physician indicates the brand is medically necessary. This legislation will create a new section pertaining to biosimilar products. When dealing with biologics, this substitution may not always be the best course of treatment for a patient. Substitution will only be permitted if certain minimal thresholds are met including a decision by the United States Food and Drug Administration that the prescribed product and the biosimilar product are interchangeable.

If you would like to co-sponsor this measure, please contact Kit Davis at kdavis@pasen.gov.