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April 19, 2010

RE: AN ACT to amend the insurance law, in relation to coverage for the HALO breast pap test to detect risk of developing breast cancer

A. 10136 (Gunther)  
S. 6894 (Johnson, C)

**MEMORANDUM IN OPPOSITION**

Submitted on behalf of the Blue Cross and Blue Shield Plans

The New York State Conference of Blue Cross and Blue Shield Plans opposes enactment of this bill, which would require insurance coverage for the use of a single, brand name device whose efficacy as a diagnostic tool still requires additional clinical study. It is poor public policy to impose such a specious mandate on private health insurance plans at a time when policymakers are struggling to control health care costs and implement federal reform.

This bill refers to a single, brand name device – the HALO breast pap test – used to perform ductal lavage, which can be performed by various other methods. Irrespective of method, however, ductal lavage has yet to be accepted as a clinically-proven method of breast cancer risk detection. The theory behind ductal lavage relies on the fact that an overwhelming majority of breast cancers begin in the ducts, and as a result, fluid collected from the ducts containing abnormal cells may provide an early warning of cancer. However, this method has yet to produce consistent clinical results. In fact, the American Society of Breast Surgeons' official

position on the issue states, “cytologic interpretation of fluid obtained by ductal lavage is ***not an approved screening tool for the detection of breast cancer. The American Society of Breast Surgeons cautions that ductal lavage should not replace standard cancer screening methods***<sup>1</sup>.” (emphasis added)

In addition, the HALO breast pap test is a branded, non-invasive method of performing ductal lavage, as compared to other minimally-invasive methods. Therefore, even should the clinical data eventually show ductal lavage to be an appropriate screening tool, statutorily mandating one particular method of collecting duct fluid (through use of a singular brand name device), to the exclusion of other approaches – some of which may not even exist yet – is ill conceived.

Finally, the addition of new mandates without the input of the Mandate Review Commission and at a time when the benefits package related to federal reform is still unclear is ill-advised. With respect to policies purchased through the insurance exchanges to be created under federal reform, New York will be responsible for reimbursing the federal government for certain costs of mandates that are above-and-beyond those required by the yet-to-be developed federal essential benefits package. While policymakers may determine in some circumstances that state benefit mandates be maintained once the federal benefit package is established it would hardly seem either a reasonable exercise of such discretion, or a responsible use of taxpayer dollars, for a mandate involving the use of a single, brand name product to facilitate testing that has yet to demonstrate clinically-proved results.

For the above reasons, we respectfully oppose enactment of this legislation.

Respectfully submitted,

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Legislative Counsel for the Blue Cross and Blue Shield Plans

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<sup>1</sup> <http://www.breastsurgeons.org/statements/index.php> (last accessed April 16, 2010)