The fundamental principle and legal mandate at the heart of this proposed bill is that of **informed consent**. Informed consent has two separate components and jurisdictions. One is the medical profession, responsible for establishing a legally binding standard of practice that guides the actual physician–patient communication concerning a specific procedure, test or treatment. The second component is the state. Each state is responsible for establishing and enforcing Medical Informed Consent law.

One can argue that a fundamental purpose of a law is to protect the public. The informed consent process, shared jointly by the physician, the patient and the state can be considered a mutual protection process, whereby all participants exchange information for the purpose of making rational decisions which ultimately affect the patient’s health. The assessment of potential benefit and harm of a specific test or treatment can be made rationally if and only if the information given to the patient is complete, accurate and true. Evidence based medicine-science (over 150 references are attached) has established that a mammogram alone, in a dense breasted woman, is not a sufficient screening test for breast cancer. The physicians of the United States have been provided with this critical information about potential harm for 10 years.

Every physician ordering a mammogram on his patient receives a written report of the results. Some content elements of this report are mandated by the Federal Government (Mammography Quality Standards Act 1992) and American College of Radiology BIRADS reporting system 1990).

The required information includes whether the screening mammogram was normal or abnormal, and any additional tests that are recommended. In addition, the standard of practice in the United States will include a statement such as the following if applicable, “this patient has dense breast tissue which may significantly lower the sensitivity of mammography to detect breast cancer.”

This same federal law requires that each and every woman who undergoes a mammogram test shall receive written notification of the results. The current federal law requires only that she be advised that her test was normal or that it was abnormal and that further testing may be indicated after discussion with her referring physician. The intent of the federal law “is to address woman’s concerns about breakdowns in communications that prevent timely diagnosis and treatment of breast disease”

Here lies the breech in the informed consent process that can result in serious harm to the patient. Although the patient’s physician has been advised of her breast density and its potential adverse consequence of under detection and that other tests are available to mitigate this limitation of mammography (breast ultrasound and Breast MRI), the patient has not. She therefore will be prevented from making her best, rational choice because information has been withheld.

The proposed notification law provides the woman having the test the information she needs to participate in an informed choice based on complete, accurate and true information.
1. **Accuracy of assessing Breast density is not reliable**
   The assignment of breast density by the radiologist is accurate for at least 80% of women. The overlap in density interpretation is only present in the transition between the scattered density and heterogeneously dense group.

2. **Breast Density as an independent risk factor is controversial**
   It is established that the degree of breast density is an independent risk factor for breast cancer, and that this risk increases with increasing breast density. To put this in context, the increased risk for the women in the heterogeneously dense category is about 1.2 times and the extremely dense 2.1 times that of the average density woman.

3. **The inclusion of breast density information to the patient could result in demands for additional non-mammographic screening tests**
   Both Breast MRI and Whole Breast Ultrasound have been scientifically validated and proven to detect more, early, invasive breast cancers than mammography alone in women with dense breast tissue. The efficacy and value of Breast MRI and ultrasound is that their sensitivities for detecting early breast cancer is independent of breast density. (American Cancer Society, American College of Radiology, Society of Breast Imaging)

   In 2007, the American Cancer Society recommended that Breast MRI be performed in addition to mammography on women in higher risk categories. At that time there was the concern that such a recommendation would lead to confusion, demands and overutilization of the technology. Our United States experience in the last 5 years has been that there has not been overutilization or confusion. The American Cancer Society, the American College of Radiology, CMS and the Insurance Industry have navigated and managed this transition efficiently. The experiences of other states that have “Dense Breast Notification Laws” in place long enough to gain a perspective have navigated the challenges with success.

   This is a good example of the collaborative success between professional, lay, governmental, and the free market forces.

   The purpose of the proposed law is to provide full disclosure to patients so that the actual outcome of the subsequent physician-patient discussion will optimize the Informed Consent process (which is mandated by state law) prior to any medical procedure or test. Valid Informed Consent requires that the information provided to all parties which include the physician and the patient are complete, accurate and true.