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Public Interest Comment[1] on the Food and Drug Administration Proposed Rule on the Mammography Quality Standards Act

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Bridget C.E. Dooling[2]

The George Washington University Regulatory Studies Center

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Introduction

Early detection of breast cancer can save lives. Mammography is one of the screening tools that has contributed to reductions in breast cancer mortality.[3] FDA has a unique role in mammography and should be commended for proposing to update its rules, particularly for those updates that reflect new technologies, such as the provisions related to digital mammography that update old regulatory terms like "x-ray film." [4] The proposed rule's breast density notification, however, raises issues of state preemption; lessons that can be learned from testing, evaluation, and

[1] This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at http://regulatorystudies.columbian.gwu.edu/policy-research-integrity.

[2] Bridget C.E. Dooling is a Research Professor at the George Washington University Regulatory Studies Center. She can be reached at bdooling@gwu.edu.

[3] *See* Rebecca L. Siegel MPH et al., *Cancer statistics, 2018*, 68 CA: A CANCER JOURNAL FOR CLINICIANS 7 (Jan/Feb 2018).

[4] Dep't of Health and Human Services, Food and Drug Administration, Mammography Quality Standards Act Proposed Rule, 84 Fed. Reg. 11,669, 11,674 (Mar. 28, 2019).

assessment of prior state action; and analysis of distributional and equity effects. FDA should consider these issues before it proceeds.

Background

Mammography is an x-ray technology that, like other imaging techniques, enables detection of breast cancer.[5] Following medical advancements in breast cancer detection in the 1960s, mammography gained traction as a valuable tool in patient care.[6] By the 1980s, its use was wide-spread but there were reports of misdiagnoses and other quality issues.[7] After a period of industry self-regulation and an effort to use grant funding from the Centers for Disease Control (CDC) and Medicare payment policy to improve quality, Congress stepped in to regulate mammography more directly.[8] It gave that responsibility to FDA in the 1992 Mammography Quality Standards Act (MQSA),[9] which has been amended twice since then, most recently in 2004.[10]

Under MQSA, it is unlawful to operate a mammography facility unless it is certified by FDA. The MQSA is distinct from FDA's other authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), [11] which apply generally to mammography *equipment* as a medical device. Under the FD&C Act, FDA regulates medical devices using restrictions like premarket review, to evaluate whether certain medical devices may be marketed, and postmarket surveillance, to monitor products and potentially to intervene after FDA has approved them for sale. The MQSA, in contrast, applies to mammography *facilities* in a broader way (e.g., licensure of personnel, patient reporting requirements). Reflecting the scope of FDA's statutory role in mammography, a 2002 GAO Report characterized FDA as having "major oversight responsibilities" under the MQSA.[12]

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[5] *See* James S. Michaelson Ph.D. et al., *Predicting the survival of patients with breast carcinoma using tumor size*, 95 CANCER 713 (Aug. 2002).

[6] Florence Houn et al., *The Mammography Quality Standards Act of 1992: History and Process*, 50 FOOD & DRUG L.J. 485, 485-86 (1995).

[7] *Id*. at 486.

[8] *Id*. at 486-87.

[9] Pub. L. No. 102-539, 106 Stat. 3547 (codified at 42 U.S.C. § 263b as amended).

[10] Mammography Quality Standards Reauthorization Act of 1998, Pub. L. No. 105-248, 112 Stat. 1864; Mammography Quality Standards Reauthorization Act of 2004, Pub. L. No. 108-365, 118 Stat. 1738.

[11] 21 U.S.C. ch. 9.

[12] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-02-532, MAMMOGRAPHY: CAPACITY GENERALLY EXISTS TO DELIVER SERVICES (2002).

FDA's most recent final rule on mammography was issued in 2002.[13] This new proposed rule contains over a dozen, wide-ranging regulatory changes related to patient and physician reporting, mammogram technology, personnel certification, recordkeeping, facility operations, and more.[14]

Regulatory Analysis of FDA's Proposed Breast Density Notification

The proposed rule would require new patient reporting about breast density.[15] The issue of breast density, and what it means for cancer risk, is nuanced. As FDA explains in its preamble, "[m]ammograms of breasts with higher density are harder to interpret than those of less dense breasts, because the dense tissue can obscure cancers."[16] The Mayo Clinic explains on its website that breast density "increases . . . risk of breast cancer, though doctors aren't certain why."[17] Patient advocates, including the late Dr. Nancy Cappello, have argued that patients should be informed of their density finding, so they can discuss options, including the potential for additional screening, with their doctors.[18] Over two-thirds of states now have some form of patient notification regarding breast density.[19]

FDA proposed to add a new notification, both for patients with low density and high density breasts. For low density breasts, FDA proposed this language:

> Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is low, not high. Follow the recommendations in this letter, and talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.[20]

For high density breasts, FDA proposed this language:

> Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is high. Some patients with high breast density may need other imaging tests in addition to mammograms. Follow the recommendations in this letter, and

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[13] Dep't of Health and Human Services, Food and Drug Administration, State Certification of Mammography Facilities Final Rule, 67 Fed. Reg. 5446 (Feb. 6, 2002).

[14] Proposed Rule, 84 Fed. Reg. at 11,671 (listing the proposed rule's major provisions).

[15] *Id*. at 11,676.

[16] *Id*. at 11,673.

[17] Mayo Clinic, Dense breast tissue: What it means to have dense breasts (Mar. 23, 2018).

[18] Denise Grady, *Obituary: Nancy Cappello, Breast Cancer Activist, Is Dead at 66*, N.Y. TIMES (Nov. 28, 2018).

[19] There is no comprehensive list of all state laws related to this issue. Two resources are https://densebreast-info.org/legislation.aspx, and https://www.areyoudenseadvocacy.org/facts.

[20] Proposed Rule, 84 Fed. Reg. at 11,685.

> talk to your healthcare provider about high breast density and how it relates to breast cancer risk, and your individual situation.[21]

As discussed below, this comment analyzes several issues raised by the proposed notifications: state preemption; lessons that can be learned from testing, evaluation, and assessment of prior state action; and analysis of distributional and equity effects.

FDA Should Clarify Whether It is Preempting State Notification Laws

FDA does not expressly state in its proposal whether its breast density notification would preempt breast density notifications required by states. For purposes of analysis, this comment assumes that FDA's proposal will fully preempt state law, based on a statement in FDA's preliminary regulatory impact analysis.[22]

Executive Order (EO) 13132 directs agencies to carefully consider whether a federal statute preempts state law.[23] As mentioned above, the MQSA delegates significant authority over mammogram facilities to FDA, but it does not unambiguously direct FDA to write a federal standard for the physician or patient reports. Rather, the MQSA conditions mammogram facility certification on the facility's assurances that the facility will prepare and provide a written report to the physician, where applicable, and to the patient.[24] It refers to this as a "requirement" for facilities while elsewhere directing the agency to establish certain "standards" in areas other than reporting.[25] This statutory ambiguity seems to be settled in practical terms, because FDA's current regulations contain reporting standards. However, FDA should take care to ensure that it does not overly construe the MQSA's preemption when conducting analysis required by EO 13132.

EO 13132 requires any federal preemption of state law to be "restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated."[26] FDA's preamble contains a Federalism section but it does not offer any analysis to support a finding that it has preempted state law to the minimum level necessary.[27] Rather, it appears to be a blanket override of state law.

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[21] *Id*.

[22] The preliminary regulatory impact analysis states that "[t]his proposed rule would enact a standard requirement that would ensure that all patients and providers receive complete and consistent breast density information in mammography reports." Dep't of Health and Human Services, Food and Drug Administration, Mammography Quality Standards Act, Preliminary Regulatory Impact Analysis at 10.

[23] Executive Order 13,132 § 4(c) (Aug. 10, 1999).

[24] MQSA § 263b(f).

[25] *Id*.

[26] Executive Order 13,132 § 4(c).

[27] Proposed Rule, 84 Fed. Reg. at 11,682.

Elsewhere, in its preliminary regulatory impact analysis, FDA argues that variation in existing state notifications makes it "unlikely that consistent and detailed density notification requirements for all patients would arise through market forces."[28] Consistency is not, in and of itself, something that justifies complete preemption under EO 13132. If it did, state-level variation would always justify federal action. Further, EO 13132 does not permit private sector cost savings as a justification for complete preemption of state law, so a single, federal standard is not justified on the grounds that it might lower compliance costs for mammography facilities that would otherwise have to comply with different state standards.

> **Recommendation 1**: FDA should clearly state whether its patient reporting requirements preempt any existing, related state notification requirements.
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> **Recommendation 2**: Consistent with EO 13132, FDA should consider whether it has adequate evidence to justify preempting state action. If FDA is unable to substantiate why complete preemption is required, it should consider flexibilities such as a waiver process. Under such a process, a state could provide evidence to FDA that its notification method is superior for its population, for demographic or any other appropriate reasons, such that a waiver from FDA's requirement is appropriate.

FDA Should Test and Evaluate Its Breast Density Notification

Long-standing U.S. policy on mandatory disclosures as a regulatory tool emphasizes that such disclosures carry costs that can be "easily overlooked," including "the effect of providing information that is ignored or misinterpreted."[29] Although FDA's effort to share breast density information with patients is undoubtedly well-intentioned, it appears to have skipped important steps: testing and evaluation.

The proposed rule preamble notes that "FDA developed two patient density paragraphs . . . with input from FDA's Risk Communication Advisory Committee."[30] There does not appear to be any documentation about that input, making it impossible to evaluate. While expert consultation and other forms of public engagement (e.g., the public comment period) are an important part of the U.S. regulatory process, they are not adequate replacements for efforts to use empirical methods to gather evidence about what works in practice. These steps are especially important for proposed information disclosures because they can reveal instances when language unintentionally confuses, misleads, or otherwise distorts the intended message.

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[28] Preliminary Regulatory Impact Analysis at 10.

[29] Office of Management & Budget, Circular A-4, Part C (Sept. 17, 2003).

[30] Proposed Rule, 84 Fed. Reg. at 11,676.

Once the government has decided to require information disclosure,[31] especially by preempting state disclosures, it has a special burden to ensure that the information disclosed can achieve its purpose. This burden arises, at least in part, from the Paperwork Reduction Act, which requires agencies to demonstrate that information disclosure requirements have "practical utility."[32] A memo from the Office of Management and Budget (OMB) implementing the Paperwork Reduction Act directed agencies, including FDA, "to engage in advance testing . . . (1) to ensure that [disclosures] are not unnecessarily complex, burdensome, or confusing, (2) to obtain the best available information about the likely burdens on members of the public (including small businesses), and (3) to identify ways to reduce burdens and to increase simplification and ease of comprehension."[33] Message testing and textual analysis tools are two powerful ways to meet these obligations.

Message Testing

The OMB memo noted above encouraged agencies to consider, for example, focus groups, cognitive testing, web-based experiments, and randomized controlled experiments to test their approaches.[34]

FDA often tests public health messages in other contexts, so much so that OMB has approved a series of "generic clearances" that allow FDA to engage with the public on an as-needed basis.[35] In one request, FDA explained that it conducts testing using multiple methods "[t]o ensure that such health communication messages have the highest potential to be received, understood, and accepted by those for whom they are intended."[36] The Division of Mammography Quality Standards, which is listed as the contact for this proposed rule, and which is part of the Center for

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[31] As explained in OMB's Circular A-4, "[i]f intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred." Mandatory information disclosures are one informational remedy, as noted by Circular A-4 and recognized in FDA's preliminary regulatory impact analysis.

[32] 44 U.S.C. § 3506. FDA recognized in its proposed rule that the patient report is covered by the Paperwork Reduction Act. Proposed Rule, 84 Fed. Reg. at 11,680.

[33] Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, for the Heads of Executive Departments and Agencies, and of the Independent Regulatory Commissions, Testing and Simplifying Federal Forms (Aug. 9, 2012).

[34] *Id*. at 2.

[35] Memorandum from Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs, for the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, Paperwork Reduction Act – Generic Clearances (May 28, 2010).

[36] Abstract, Testing Communications on Medical Devices and Radiation-Emitting Products, OMB Control No. 0910-0678.

Devices and Radiological Health, has access to several of these clearances,[37] none of which appear to have been used for the purpose of testing the breast density component of the proposed patient report.[38] FDA could also have sought separate OMB approval to collect information to evaluate the patient report, but that does not appear to have happened, either.[39]

> **Recommendation 3**: If FDA conducted message testing on its breast density notification language, it should make those materials (e.g., research questions, protocol, findings) available for public comment.
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> **Recommendation 4**: If FDA did not conduct message testing activities, it should undertake sufficient testing to determine whether the breast density notification is capable of achieving its intended purpose. FDA has several existing generic clearances available to facilitate this testing under the Paperwork Reduction Act.

Textual Analysis Tools

Apart from the message testing described above, textual analysis can be a quick and low-cost way to evaluate the linguistic content of messages. This can help reveal whether proposed messages are readable and understandable. FDA has demonstrated attentiveness to these concepts in other domains, particular in its rules for obtaining informed consent.

There, FDA regulations require that "information that is given to the subject or the representative shall be in language understandable to the subject or the representative."[40] In draft guidance explaining this provision, FDA elaborates that "understandable" means "the information presented to potential subjects is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms)."[41] The draft guidance recognizes that "more than one-third of U.S. adults, 77 million people, have basic or below basic health literacy"[42] and that this "[l]imited health literacy affects adults in all racial and ethnic groups."[43]

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[37] *E.g.*, Focus Groups as Used by the Food and Drug Administration, OMB Control No. 0910-0497; Testing Communications on Medical Devices and Radiation-Emitting Products, OMB Control No. 0910-0678; Generic FDA Rapid Response Surveys, OMB Control No. 0910-0500.

[38] Based on searches of www.reginfo.gov, which contains records of OMB's approved information collections.

[39] *Id*.

[40] 21 C.F.R. 50.20.

[41] Food & Drug Administration, Informed Consent Information Sheet (Draft Guidance) at 5 (July 2014).

[42] *Id*.

[43] *Id*. The studies FDA cites, in the draft guidance, as support for its interpretation of "understandable" in the informed consent context are not limited to situations related to human subjects testing. Rather, they apply in general, presumably including in the context of breast density information.

We do not have perfect measures of concepts like "understandability," but there are some textual analysis tools that offer a way to gauge it. In fact, others have already done this in the context of breast density notifications. Researchers at Boston University studied a suite of 23 state breast density notifications that predate this FDA proposal.[44] They used two readability scales, known as Flesh-Kincaid and Dale-Chall, and one understandability scale, the Patient Education Materials Assessment Tool, to evaluate those state notifications.[45] The results were strikingly poor on both readability and understandability. On readability, most notifications exceeded the recommended reading level of grade 7-8. In terms of understandability, all scored poorly.[46] States vary in their exact notification language, and tend to be longer than FDA's proposed language, but many are similar enough to FDA's proposed language that the results noted above counsel towards careful consideration.[47] In short, the readability and understandability findings from these researchers and others[48] should inform FDA's proposal, but FDA does not reference them.

Further, FDA has recognized the value of "understandable" messages in its own informed consent regulations. Those rules apply to human subjects testing, a context in which FDA aims to take great care of potential study participants. FDA is not likely bound by its informed consent rules in this context. However, if FDA believes that breast density notification is a serious enough issue to require mandatory reporting, then it should use textual analysis tools to evaluate its own notification language.

> **Recommendation 5**: FDA should acknowledge the findings of the Boston University study noted above and other existing research on the readability and understandability of public health messaging. In addition, FDA should apply textual analysis tools to its own proposed notification and consider how to address any issues that they raise with understandability and readability.

FDA Should Take Advantage of Prior State Action to Learn What Works

In addition to the testing and evaluation noted above, FDA has a tremendous opportunity to study how breast density notifications have worked in the states. As noted above, more than 35 states already require some form of breast density notification. A recent recommendation from the Administrative Conference of the United States explored methods that agencies can use to learn

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[44] Nancy R. Kressin, PhD, Christine M. Gunn, PhD, & Tracy A. Battaglia, MD, MPH, *Content, Readability, and Understandability of Dense Breast Notifications by State*, 315 J. AM. MED. ASS'N 1786 (Apr. 26, 2016).

[45] *Id*.

[46] *Id*.

[47] Specific state notification language can be seen by clicking on various states shown in the map available at densebreast-info.org/legislation.aspx.

[48] *See, e.g.*, Ami Saraiya, MD, Grayson L. Baird, PhD & Ana P. Lourenco, MD, *Breast Density Notification Letters and Websites: Are They Too "Dense"?*, 16 J. AM. C. RADIOLOGY 717 (May 2019).

from regulatory experience. One part of this recommendation is especially relevant to FDA's mammography proposal:

> Agencies can also undertake observational studies prior to creating new rules. An agency might, for example, employ a cross-sectional research design by looking at variation in existing policies at the state level (or perhaps in other countries), taking to heart Justice Louis Brandeis's observation that "a . . . state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." In fact, Congress has, on numerous occasions, directed agencies to analyze state-by-state variation to help determine optimal policies.[49]

State-level variation is useful to FDA in at least three ways. First, FDA could evaluate how the language of different notifications leads to different outcomes or unintended consequences. Second, FDA could compare the public health effects in states with and without notification requirements. Some of this is already in the medical literature, but FDA does not reference it.[50] Third, FDA could evaluate how state-level data sheds light on whether the benefits of notification of low breast density, as distinct from high density, outweigh the potential problems of confusion and disruption to patients.[51]

FDA does not necessarily have to do all of this research on its own. Rather, FDA could consider partnering with an academic or other research institution, or it could provide research questions for researchers to use as they embark on new studies. Such an undertaking is consistent with new federal agency obligations under the Foundations for Evidence-Based Policymaking Act,[52] which requires agencies to prepare an "evidence-building plan" or learning agenda.

> **Recommendation 6**: FDA should take advantage of prior state action to evaluate what works best for public health. This could include, at a minimum, an assessment of existing medical literature, and also FDA's own assessment, perhaps in partnership with other entities.

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[49] Administrative Conference of the United States, Learning from Regulatory Experience (Recommendation 2017-6) at 7 (internal footnotes omitted).

[50] *See, e.g.*, Susan H. Busch, PhD et al., *Association of State Dense Breast Notification Laws With Supplemental Testing and Cancer Detection After Screening Mammography*, 109 AM. J. PUB. HEALTH 762 (May 1, 2019); Michal Horný et al., *Dense Breast Notification Laws: Impact on Downstream Imaging After Screening Mammography*, MED. CARE RESEARCH & REV. (Jan. 2018).

[51] Nevada, for example, only requires notification for high density results. *See* https://densebreast-info.org/legislation.aspx.

[52] Pub. L. No. 115-435.

FDA Should Consider the Distributive and Equity Effects of Its Notification

In mammography, like so many other areas of public health that FDA regulates, there are "risk-risk" trade-offs, a concept that means that an action that tries to reduce one risk might inadvertently increase another. An example from another aspect of breast health is illustrative. A study of false positives showed that certain actions can have different effects on different groups of people. In a "false positive," following a mammogram a patient is recalled for additional imaging or biopsy that does not yield a breast cancer diagnosis. A 2008 study found that 93% of white women were "likely" or "very likely" to continue getting annual mammograms despite receiving a false positive result. By comparison, the estimates were 71% for Hispanic women and 80% of black women.[53] These differences deserve attention.

Although breast density notification is not the same as a false positive, they have similarities. First, they both involve patient notifications. Second, they are both providing what is reasonably considered to be alarming information. A full summary of the existing medical research on this topic is beyond the scope of this comment and the expertise of this commenter. But as a public health agency, FDA has a responsibility to acknowledge and weigh the undoubtedly complex factors that could be leading to the results noted above. FDA's proposed rule, however, does not acknowledge this literature, which suggests that there might be sociodemographic differences in how messages about mammography are received. The GAO recognized that sociodemographic differences have an effect on mammography as far back as 2006,[54] and FDA should, too.

FDA does not necessarily have to be able to explain this result fully to take it into account. FDA's objective, in the context of its mammography rule, should be to ensure that its notification does not exacerbate these issues. It would be a poor result, indeed, if well-intentioned mandatory breast density notification language disproportionately discouraged women of color from getting mammograms as directed.

> **Recommendation 7**: FDA should review and consider the medical and other public health literature on differences in the way that messages about mammography are received. This should, in turn, inform its breast density notification. In particular, and at a minimum, FDA should test the notification with an adequate sample of black and Hispanic women, who have been shown to have a more significant negative reaction to similar messages.

Executive Order 12866 requires agencies to "select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages;

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[53] Nazia F. Jafri, MD et al., *Screening Mammography: Does Ethnicity Influence Patient Preferences for Higher Recall Rates Given the Potential for Earlier Detection of Breast Cancer?*, 249 RADIOLOGY 785 (Dec. 2008).

[54] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-724, MAMMOGRAPHY: CURRENT NATIONWIDE CAPACITY IS ADEQUATE, BUT ACCESS PROBLEMS MAY EXIST IN CERTAIN LOCATIONS (2006).

distributive impacts; and equity), unless a statute requires another regulatory approach."[55] FDA's proposed regulatory impacts analysis does not discuss equity at all, and it only analyzes effects on Medicare and Medicaid spending under its distributional analysis.[56] By not analyzing these issues, FDA misses an opportunity to consider potential unintended consequences of its proposed notification.

> **Recommendation 8**: FDA should revise its regulatory impact analysis to include a discussion of how the studies noted above inform the distributional and equity effects of its proposal, and modify the rule as appropriate.

Conclusion

Early detection of breast cancer, using mammography or other means, can save lives. Congress conferred special burdens on FDA when it enacted the MQSA, enmeshing FDA into the provision of medical care in a way that is unique from FDA's other statutory responsibilities under the FD&C Act. In exercising this authority to require breast density reporting to patients, FDA has a special duty to take care with the language it mandates.

In the eight recommendations above, and summarized below, this comment encourages FDA to clarify whether and how its action preempts state law; to incorporate testing, evaluation, and assessment of prior state action into the notification, and to acknowledge and consider potential distributional and equity effects beyond what it has already described.

Taking these steps will bring the policy more into line with existing U.S. regulatory policy and, more importantly, offer greater assurance that the notification will improve public health.

Summary of Recommendations

Issue		Recommendation
State Preemption	**1.**	FDA should clearly state whether its patient reporting requirements preempt any existing, related state notification requirements.
	2.	Consistent with EO 13132, FDA should consider whether it has adequate evidence to justify preempting state action. If FDA is unable to substantiate why complete preemption is required, it should consider flexibilities such as a waiver process. Under such a process, a state could provide evidence to FDA that its notification method is superior for its population, for demographic or any other appropriate reasons, such that a waiver from FDA's requirement is appropriate.

[55] Executive Order 12,866 § 1(a) (Sept. 30, 1993) (emphasis added).
[56] Preliminary Regulatory Impact Analysis at 38-39.

Testing & Evaluation	**3.**	If FDA conducted message testing on its breast density notification language, it should make those materials (e.g., research questions, protocol, findings) available for public comment.
	4.	If FDA did not conduct message testing activities, it should undertake sufficient testing to determine whether the breast density notification is capable of achieving its intended purpose. FDA has several existing generic clearances available to facilitate this testing under the Paperwork Reduction Act.
	5.	FDA should acknowledge the findings of the Boston University study noted above and other existing research on the readability and understandability of public health messaging. In addition, FDA should apply textual analysis tools to its own proposed notification and consider how to address any issues that they raise with understandability and readability.
Learning from the States	**6.**	FDA should take advantage of prior state action to evaluate what works best for public health. This could include, at a minimum, an assessment of existing medical literature, and also FDA's own assessment, perhaps in partnership with other entities.
	7.	FDA should review and consider the medical and other public health literature on differences in the way that messages about mammography are received. This should, in turn, inform its breast density notification. In particular, and at a minimum, FDA should test the notification with an adequate sample of black and Hispanic women, who have been shown to have a more significant negative reaction to similar messages.
Distributive & Equity Effects	**8.**	FDA should revise its regulatory impact analysis to include a discussion of how the studies noted above inform the distributional and equity effects of its proposal, and modify the rule as appropriate.