

FDA Proposal to Regulate Lyme Lab Tests Chartbook

Conducted 2014-2015



A **lymedisease.org** Survey

7989

Total Responses

Date Created: October 21, 2014

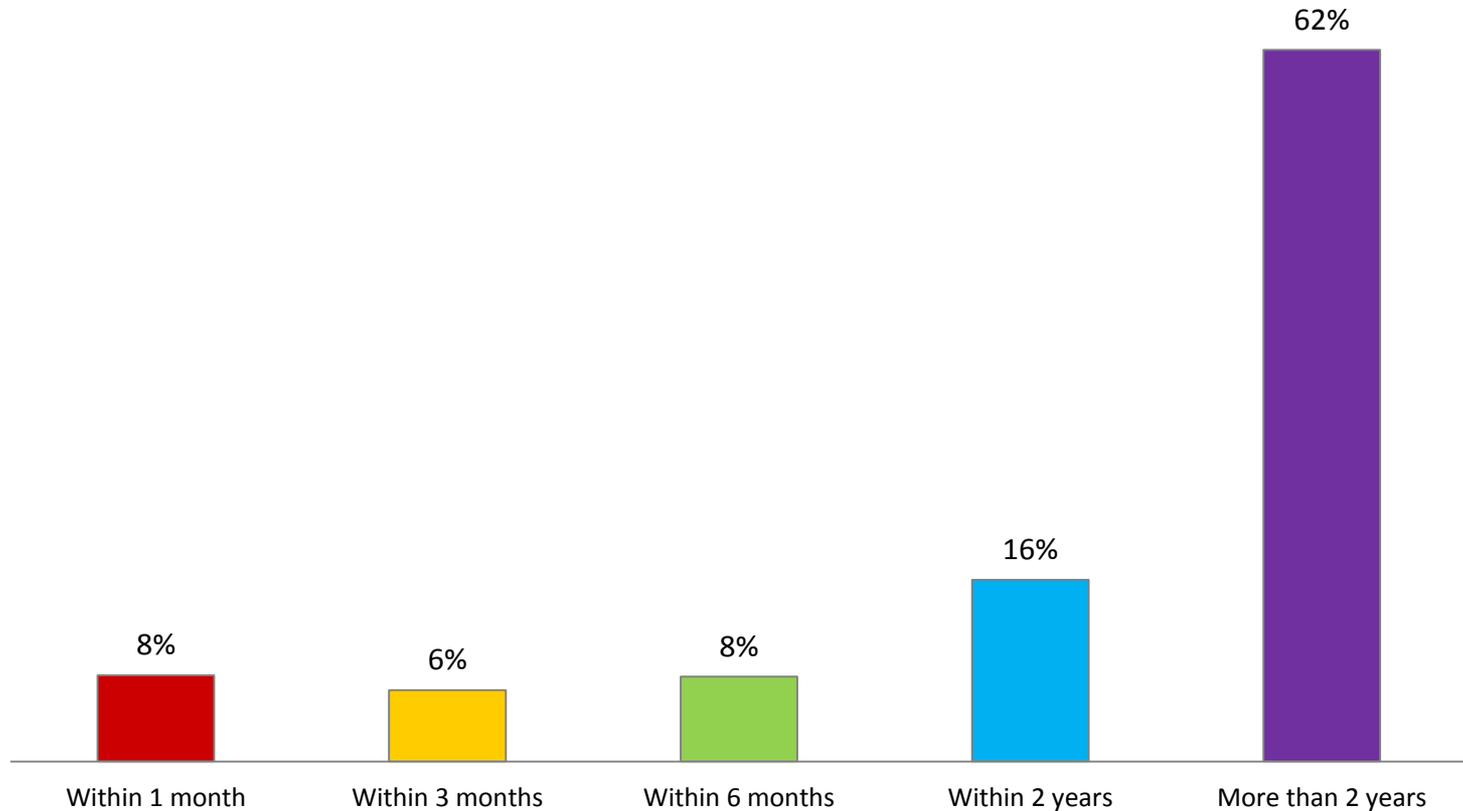
In 2014, the Food and Drug Administration announced that it was going to start regulating laboratory developed tests (LDTs). In Lyme disease, many patients rely on LDTs, like those provided by IGeneX, because the sensitivity of commercial lab tests is less than 50%. LymeDisease.org scheduled a meeting to talk with the FDA and launched a patient survey to determine what Lyme patients regard as being the most important issues in testing. LDo presented the results of the survey, which drew over 4,000 responses in two weeks, to the FDA at its meeting and subsequently at an FDA hearing on the topic. In the end, it drew close to 8,000 responses.

The survey found that patients were more concerned with remaining ill, not being diagnosed and treated and not being able to improve ability to function than they were with minor treatment side effects they might incur as a result of a false positive test. They also valued lab test innovation far more highly than rigorous premarket accuracy testing. These result are not surprising since 56% of patient reported delayed diagnosis, 29% reported denied insurance claims, and 28% reported being denied disability due to a negative lab test.

When asked what should be done to protect patients if lab tests generated either false negative or false positive results, 85% of patients favored telling patients the risks associated with false test results and permitting patient to make an informed choice regarding whether to take the test. Only 15% believed that tests should be pulled off the market.

Delayed diagnosis is a big problem in chronic Lyme disease.

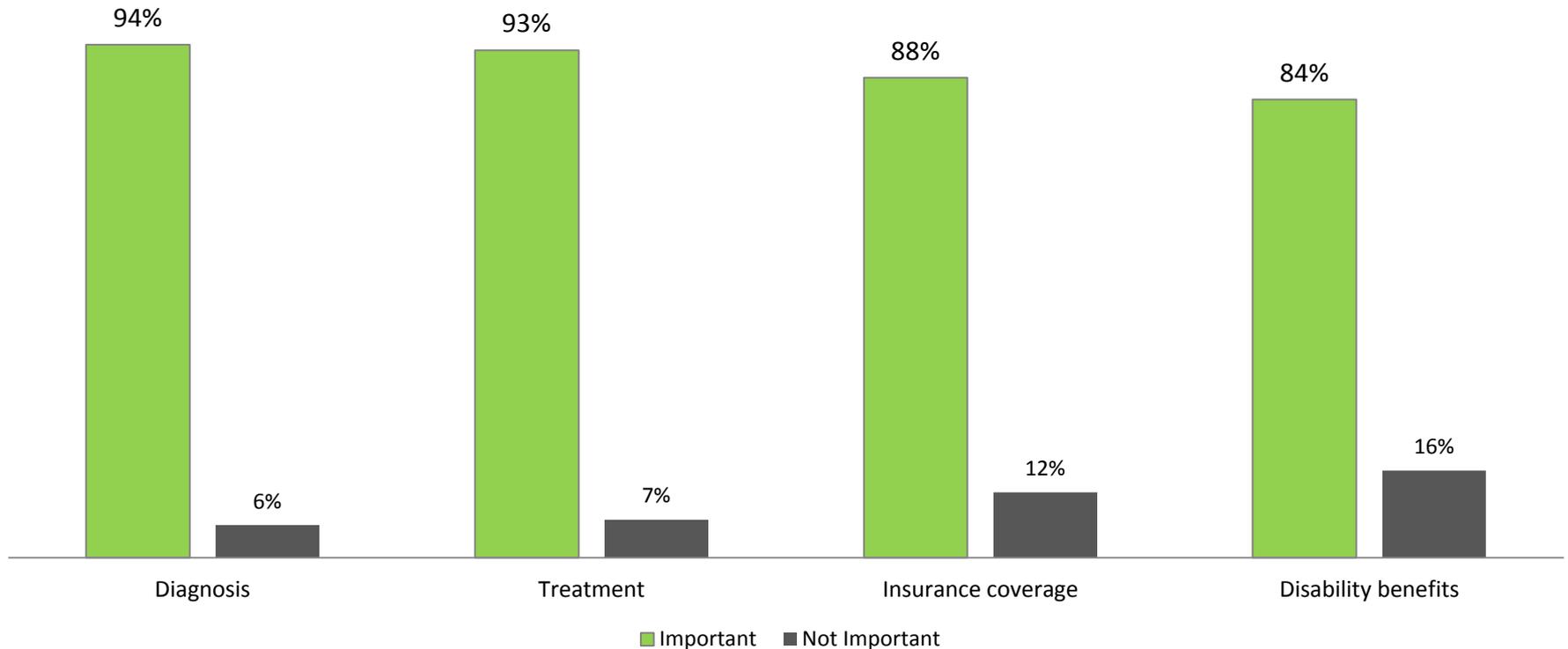
62% of CLD patients are not diagnosed within 2 years.



Obtaining a positive lab test is an access to care issue for patients with CLD.

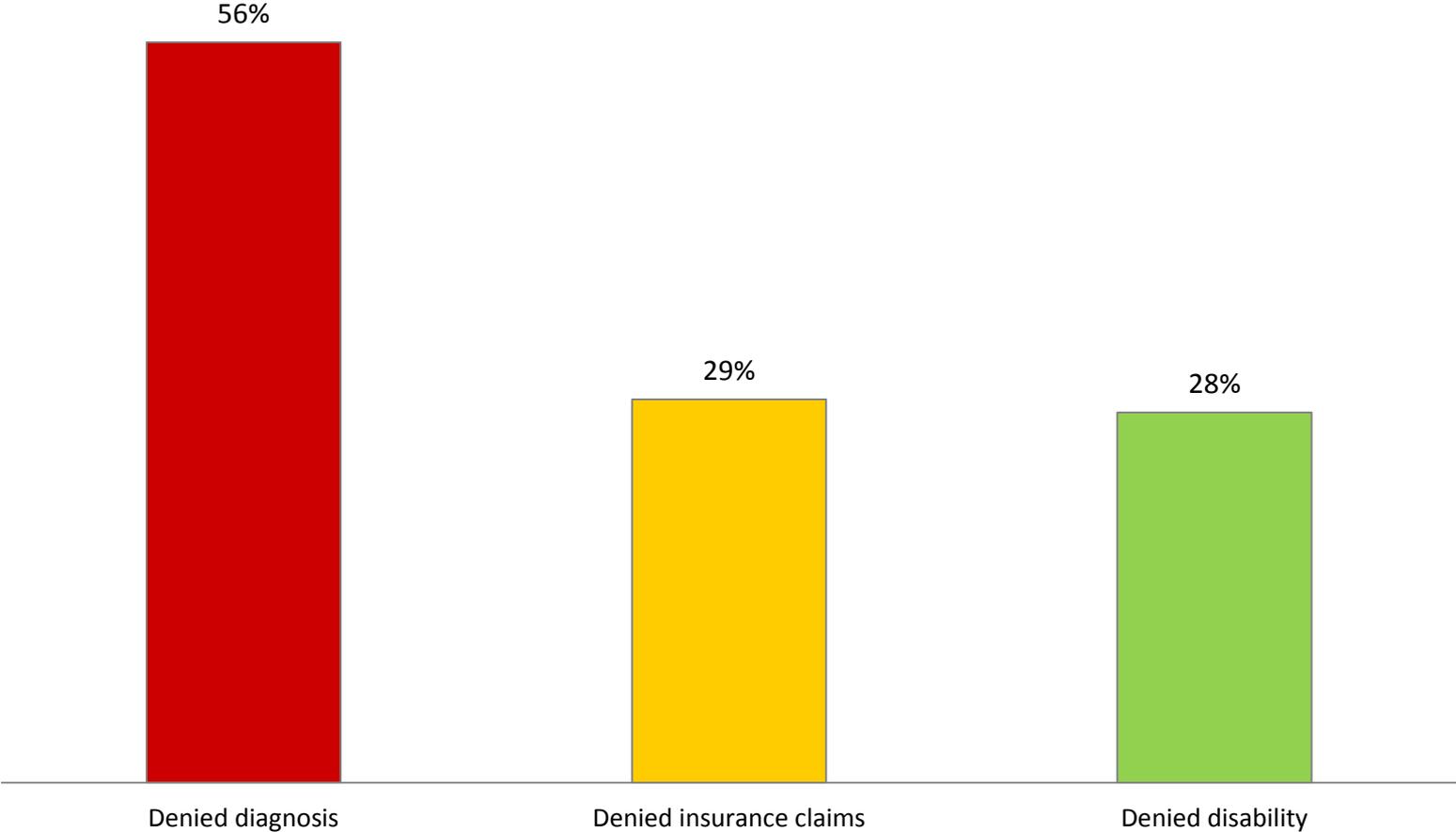
80% of Lyme patients are diagnosed clinically with supporting lab tests.

CLD patients regard positive lab tests as important for diagnosis, treatment, insurance, and disability.

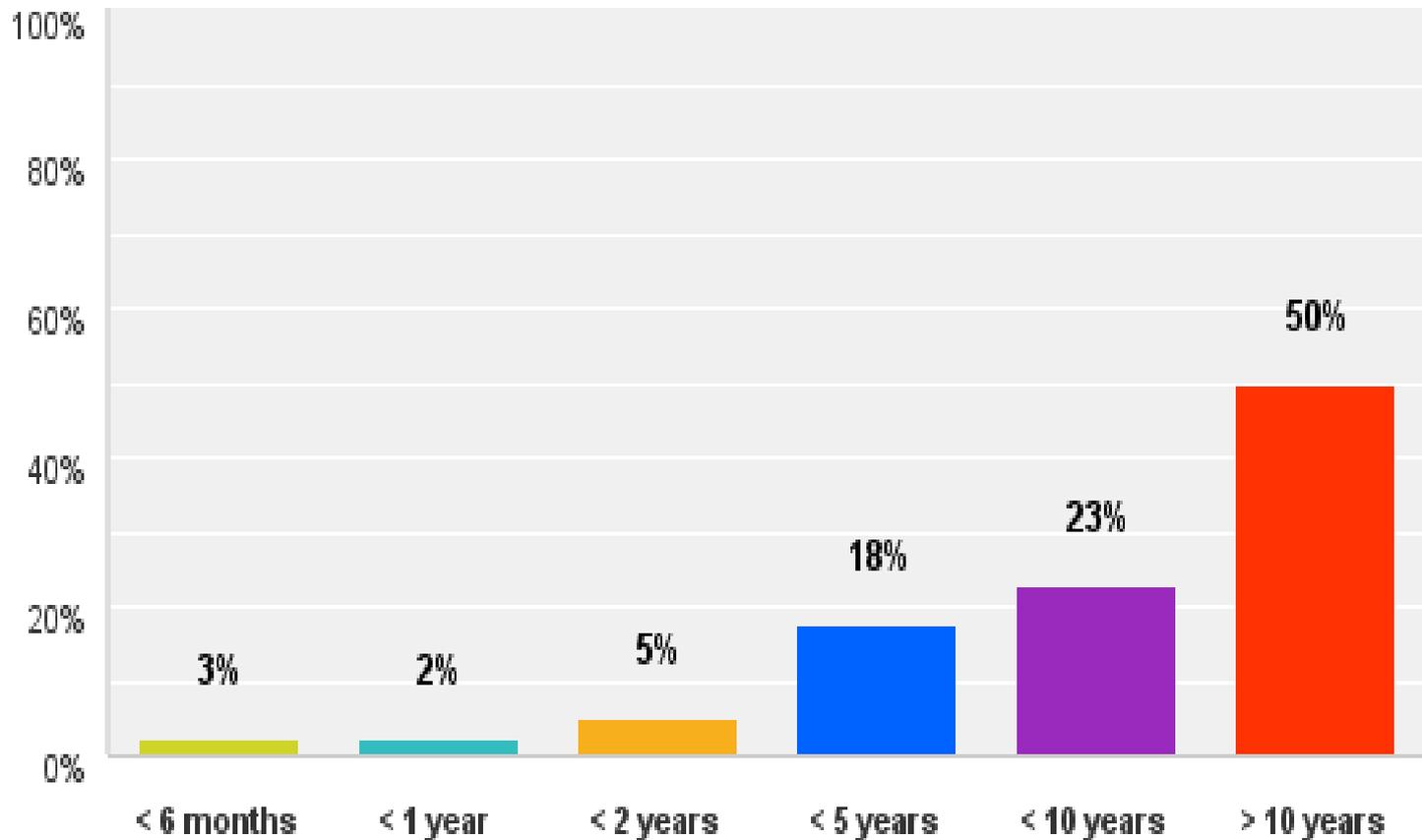


CLD patients without a positive lab test are denied care.

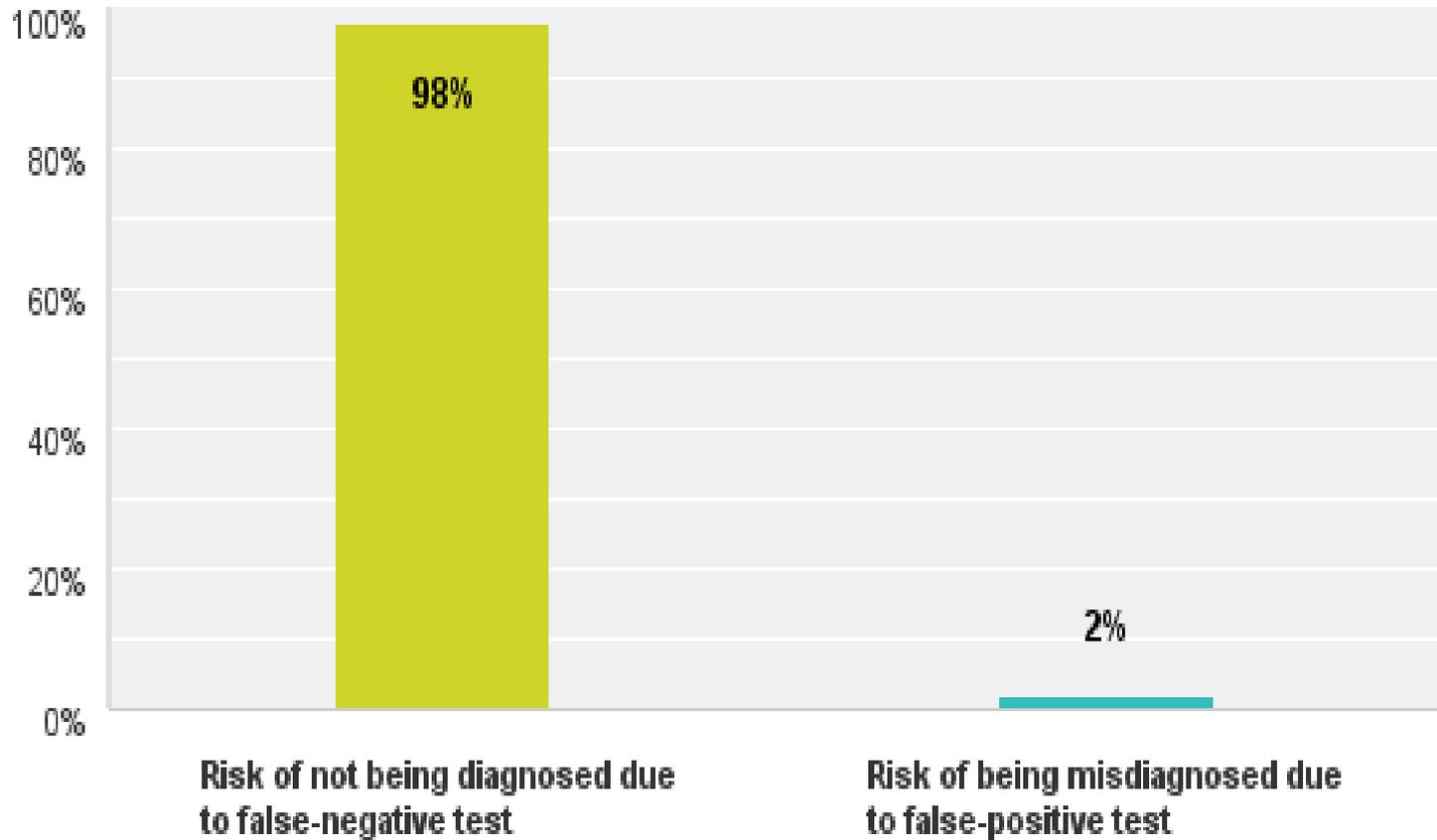
CLD patients denied diagnosis, insurance or disability benefits due to not having positive lab test.



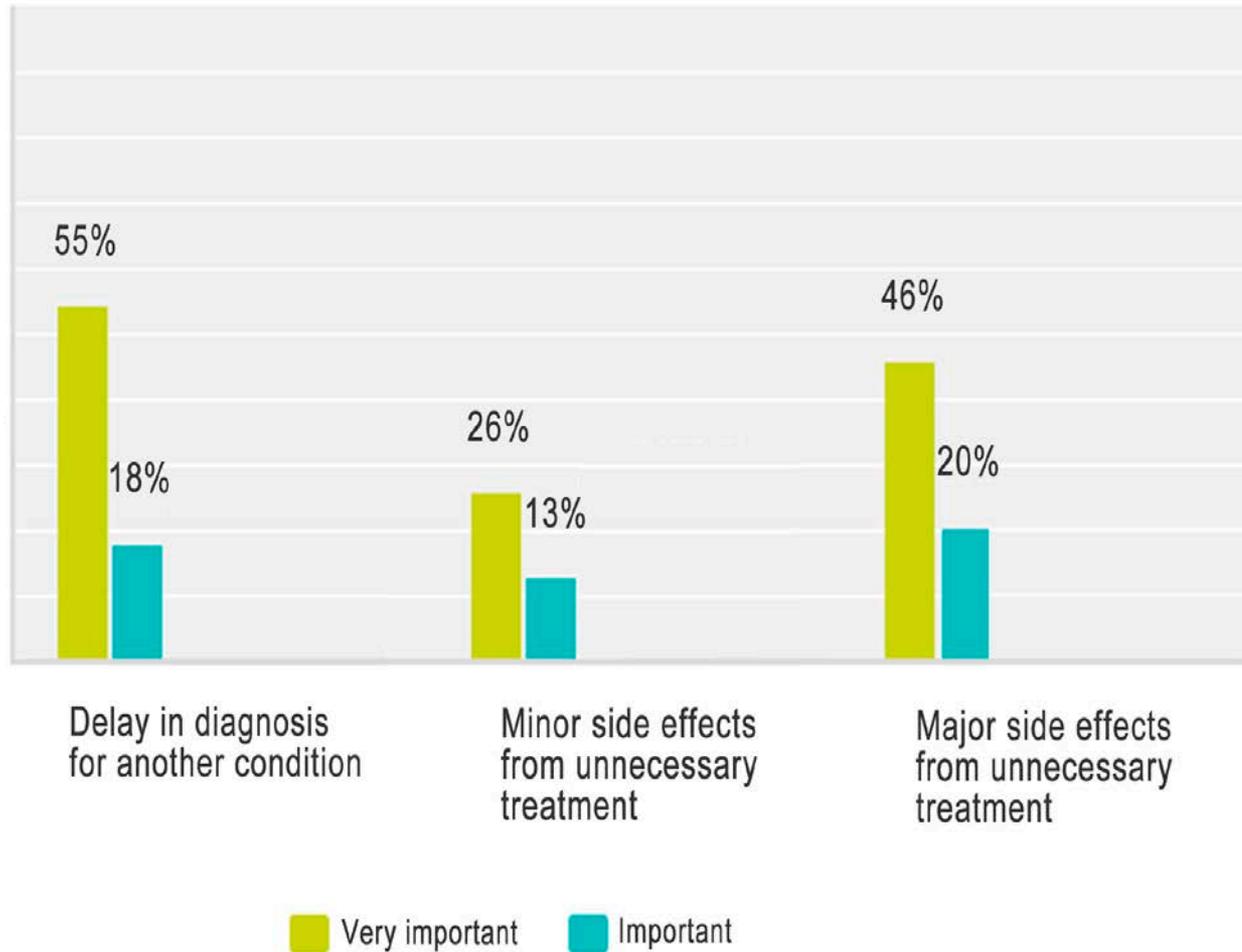
How long have you had Lyme disease? I've had Lyme



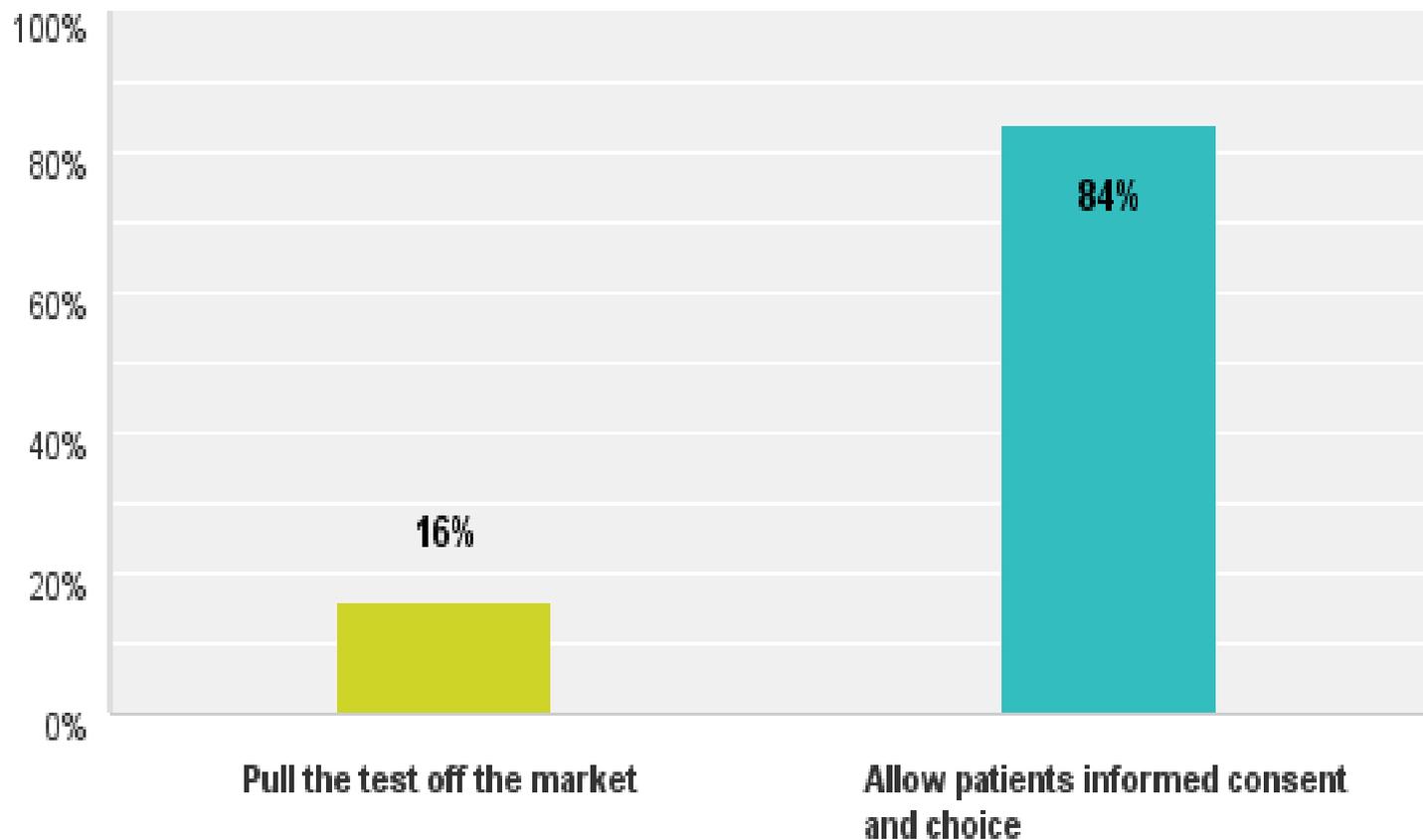
What do you think is the greater risk to patients:



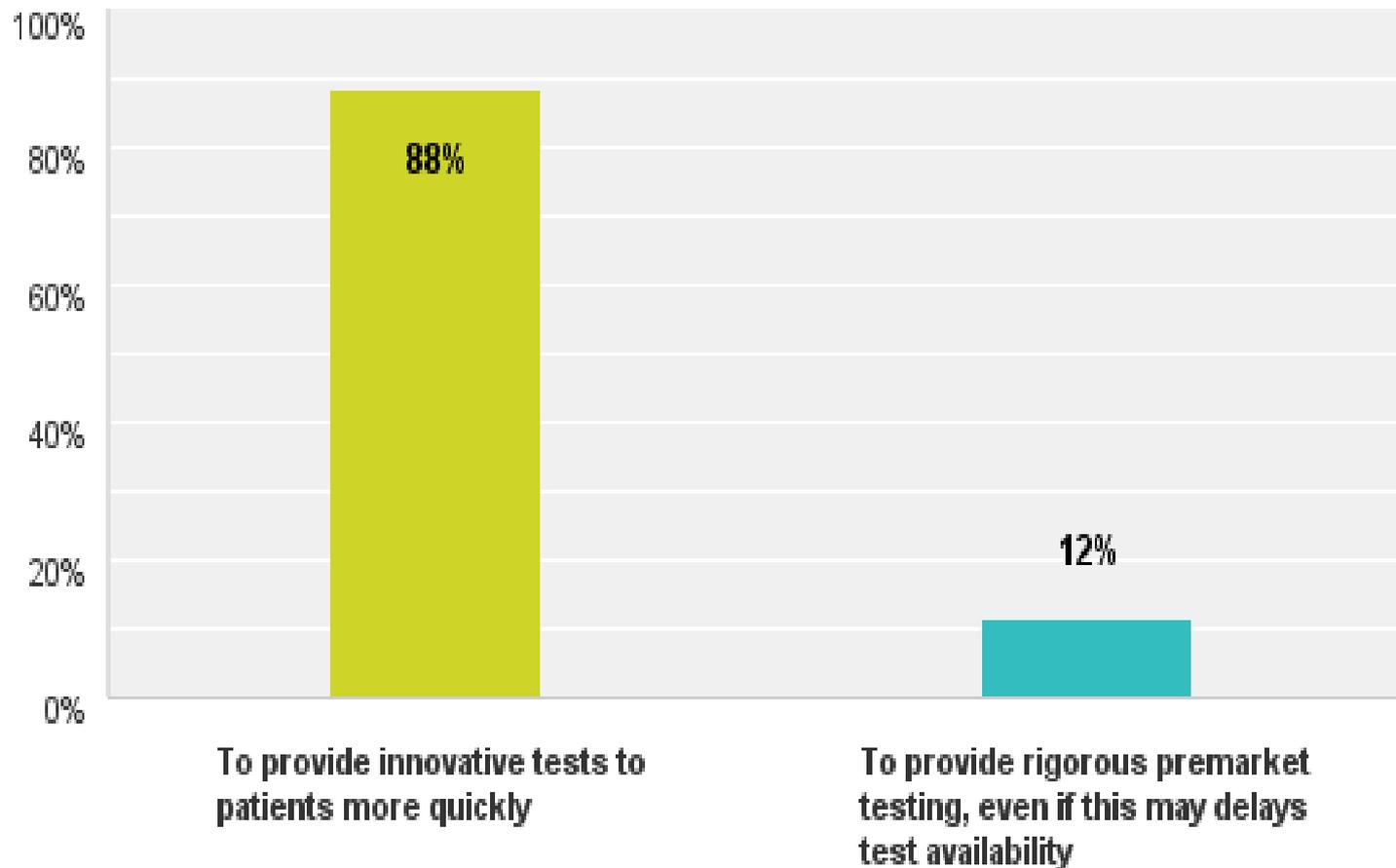
How important are the following risks of an incorrect Lyme diagnosis?



If a Lyme disease diagnostic test is not completely accurate, the FDA should:



What is the most important aspect of Lyme disease test development:



Notes:

This survey was conducted over the internet in the United States between October 21, 2014 and February 2015. It drew approximately 8,000 responses in that period.

The survey was answered by patients living in the United States who were 18 years old or older. The average age was 50 and 82% of respondents were female.

For more than ten years, LymeDisease.org has been conducting patient surveys to bring the perspective of patients to the forefront. You can read the results of two of our peer reviewed surveys listed below or follow the results of our other surveys at LymeDisease.org. In 2015, LDo launched its big data project, MyLymeData, which is a PCORnet project.

For further information, contact the lead author, Lorraine Johnson, JD, MBA at lbjohnson@lymedisease.org.

Johnson L, Aylward A, Stricker RB. Healthcare access and burden of care for patients with Lyme disease: a large United States survey. Health Policy. 2011 Sep;102(1):64-71. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21676482>.

Johnson L, Wilcox S, Mankoff J, Stricker RB. Severity of chronic Lyme disease compared to other chronic conditions: a quality of life survey. PeerJ. 2014; 2. Available from: <http://dx.doi.org/10.7717/peerj.322>.

Visit LymeDisease.org for more information about our patient surveys and our big data project, MyLymeData.



A **lyme**disease.org Survey
