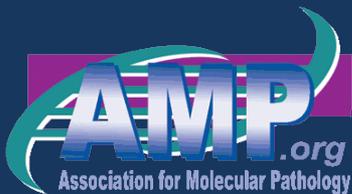


AMP Response to NIH GTR RFI - Survey of Clinical Molecular Laboratories

V.M. Pratt, Ph.D., FACMG
AMP Professional Relations
Committee



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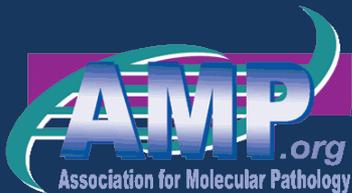
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AMP 2010 Annual Meeting

Conflict of Interest Disclosure

Victoria Pratt

- Employment, Stock options – Quest Diagnostics



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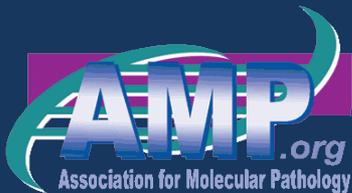
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AMP survey

- 63 respondents
 - 93% worked in a clinical laboratory
 - 48% university
 - 32% reference/commercial

Manufacturers responded that they were not intended audience

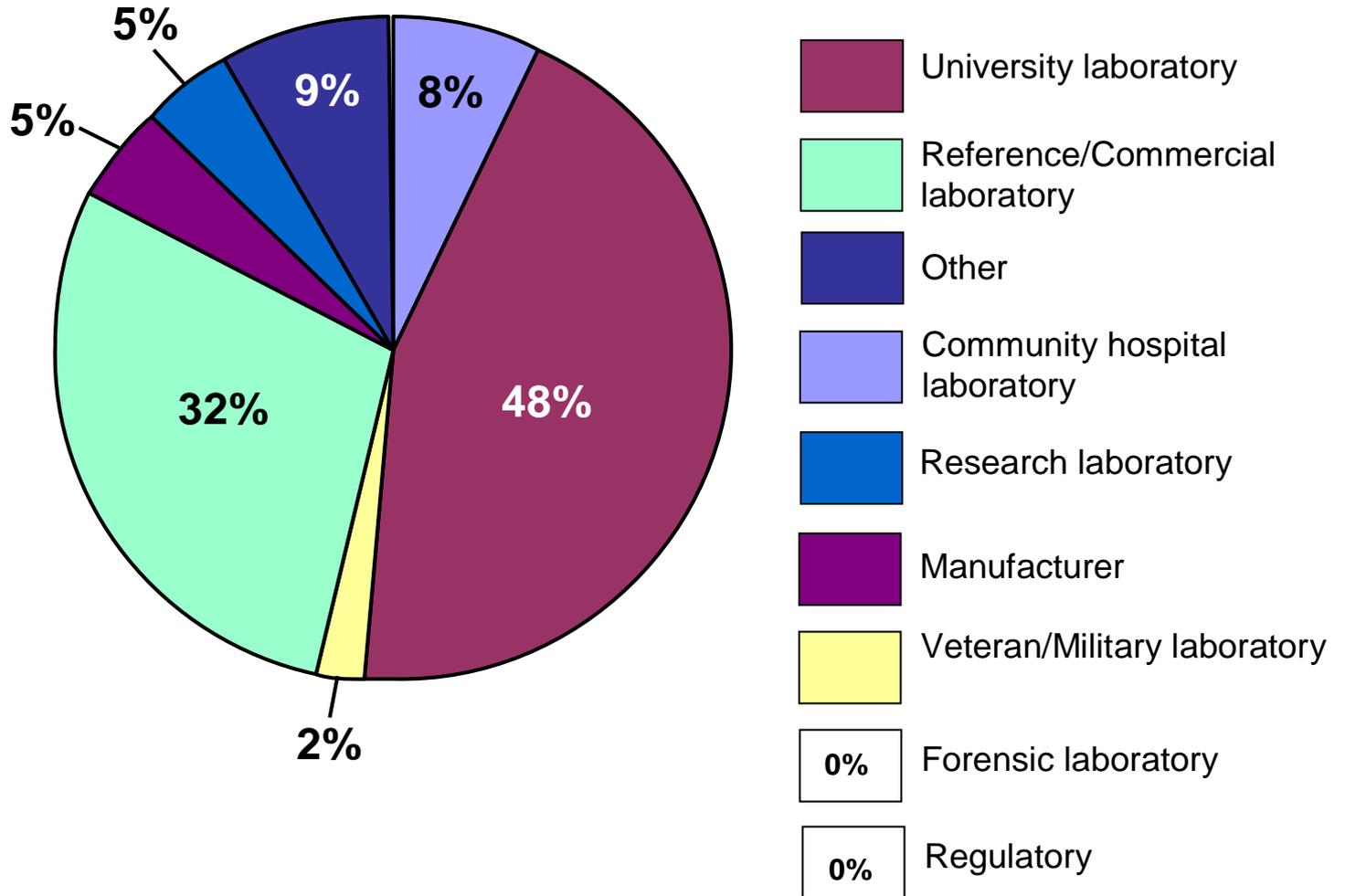


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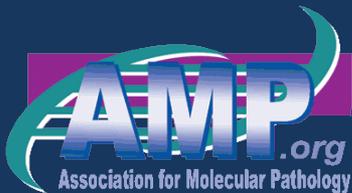
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Respondents' work environment?



AMP Survey

- 83% had heard of the NIH's Genetic Test Registry (GTR)
- 72% were interested in participating

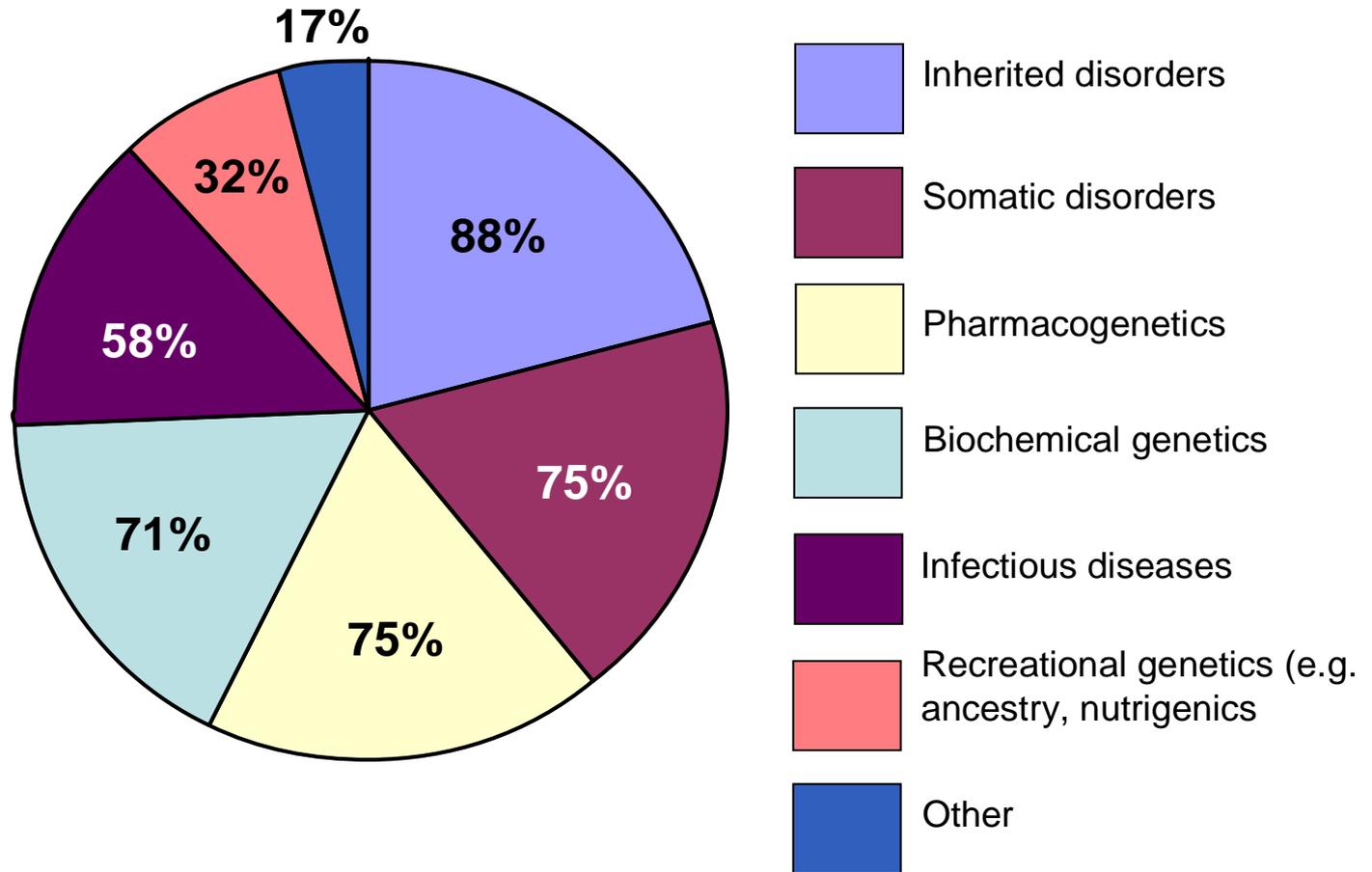


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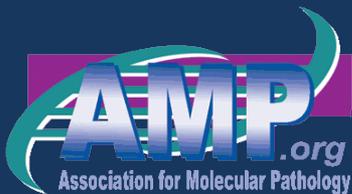
What tests do you believe a Genetic Test Registry should include?



Other tests to include in GTR

- Cytogenetics
- HLA
- All clinical tests

AMP members understand that the definition of genetic or genomic tests encompasses more than traditionally inherited genetic disorders.



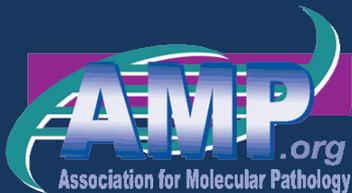
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One registry?

- Research and clinical laboratories have different goals and oversight

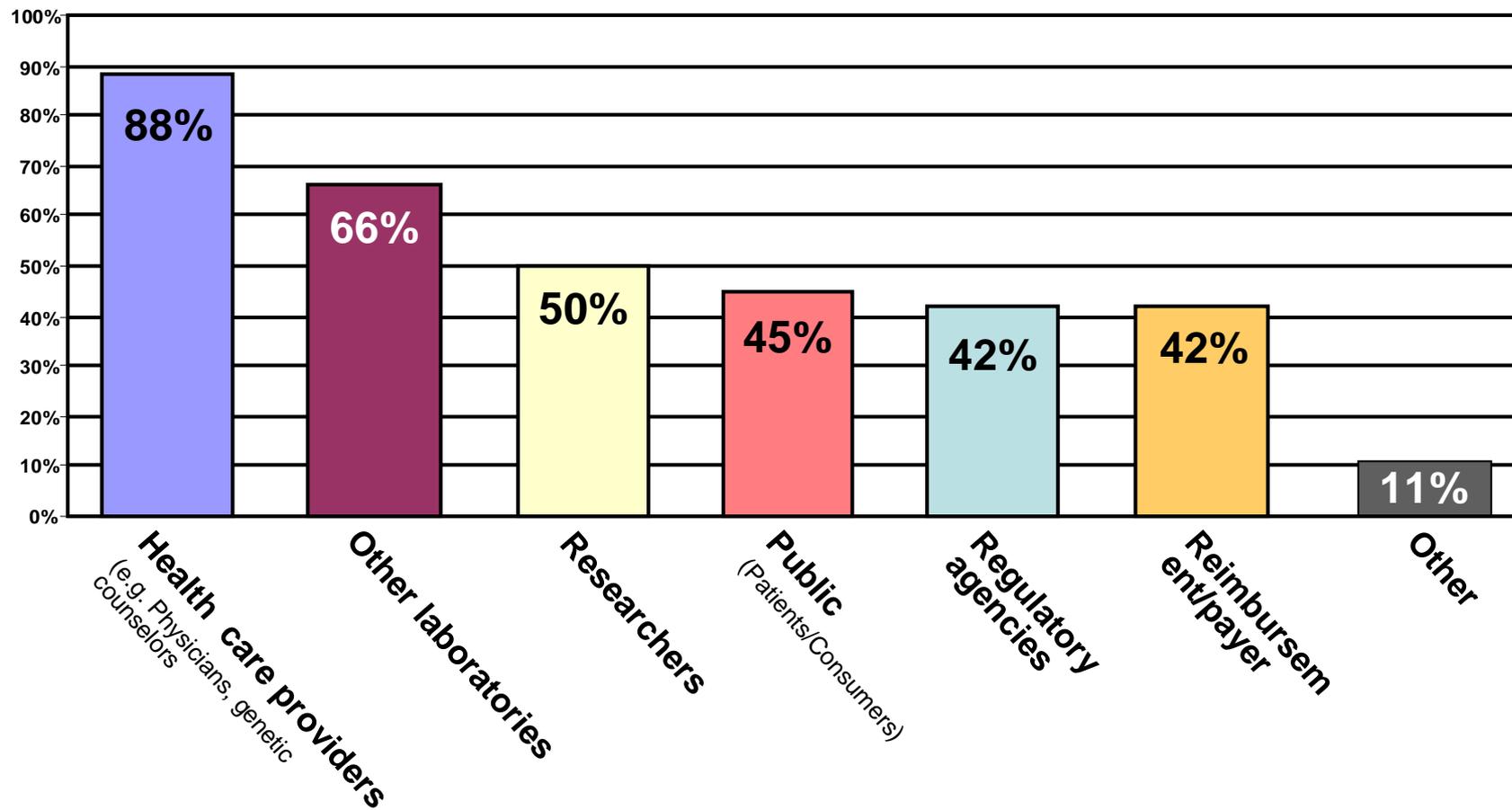


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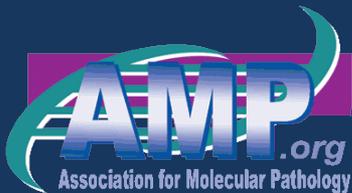
If you participated in the GTR, whom do you believe would be the most relevant audience?



A registry could be a resource for healthcare providers

What to provide the GTR?

- Elements similar to AMP's current test registry were agreeable by respondents
- Generally low interest in providing performance characteristics
- Less willing to provide confidential or proprietary information

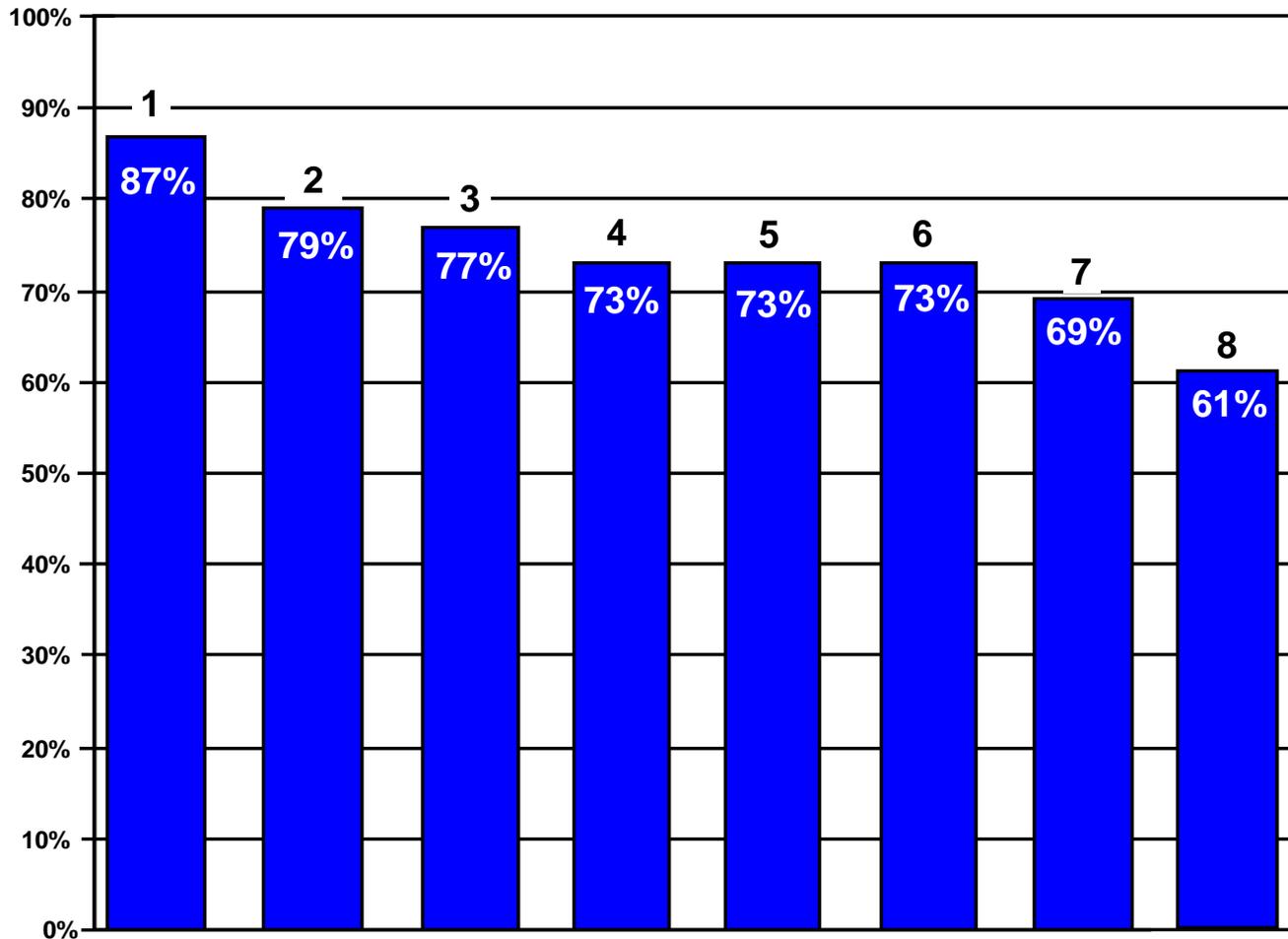


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What would you be willing to provide to the GTR?



1. Test name (gene[s] being tested)

2. Mutations/analytes tested

3. Contact information

4. Method

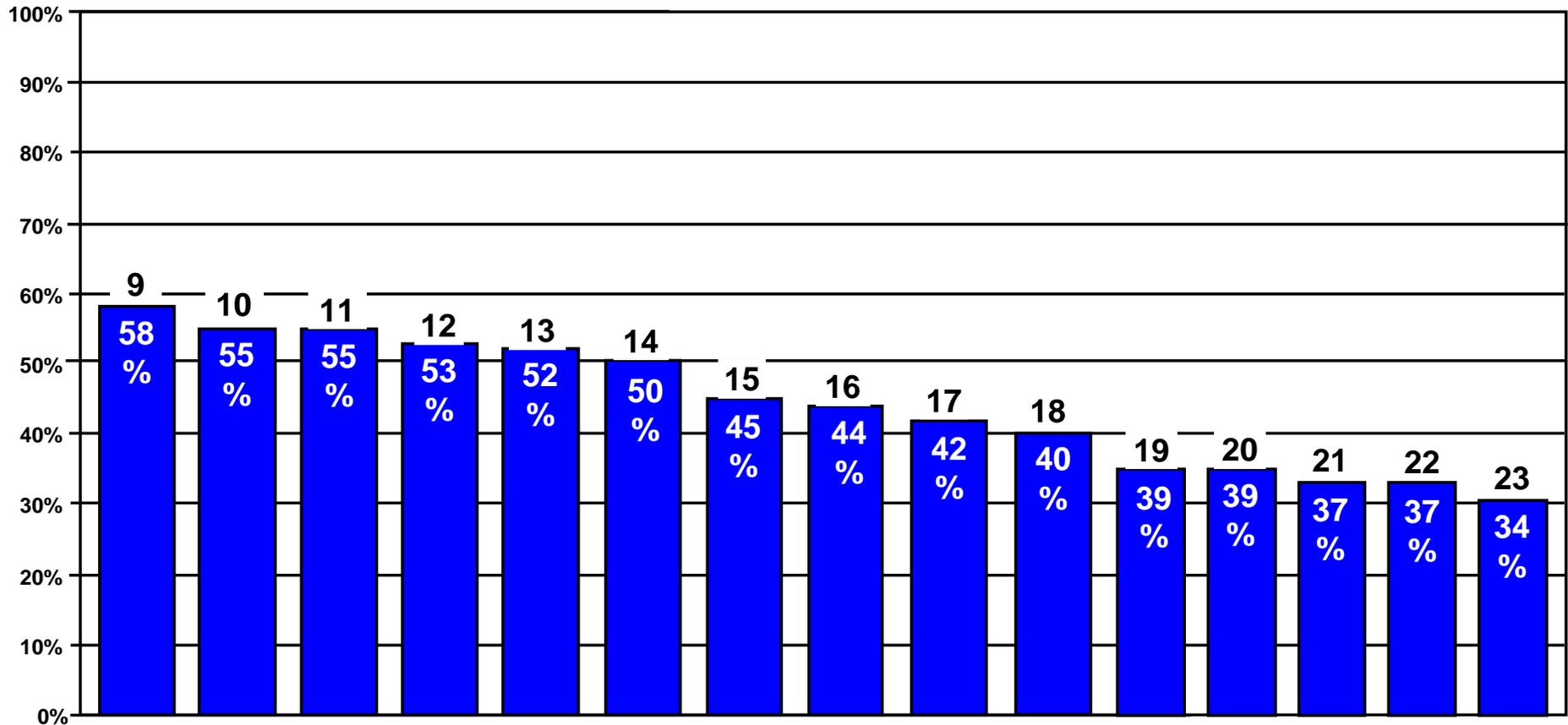
5. Specimen types

6. Specimen requirements

7. Certifications (e.g. CAP, CLIA, NYSDOH, ISO)

8. Intended use

What would you be willing to provide to the GTR?

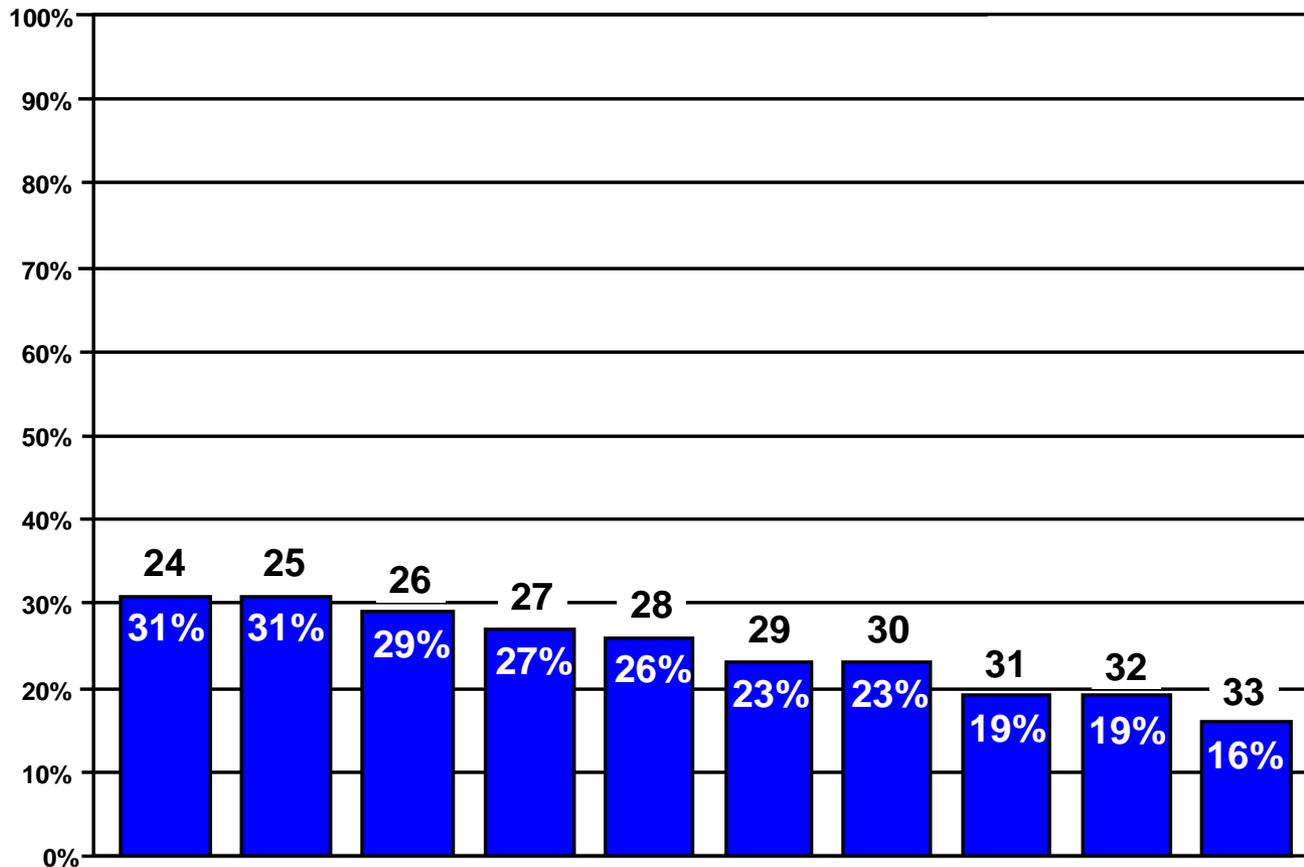


- 9. Test limitations
- 10. Analytical sensitivity
- 11. Analytical specificity
- 12. Clinical use category
- 13. CPT codes

- 14. Regulatory status of assay/reagents
- 15. Limit of detection
- 16. Reference range
- 17. Accuracy
- 18. Clinical utility

- 19. Clinical validity
- 20. Laboratory personnel certifications
- 21. Precision
- 22. Quality measures
- 23. Prevalence

What would you be willing to provide to the GTR?



24. Positive & negative predictive value

25. Lab reports

26. Clinical specificity

27. Clinical sensitivity

28. Marketing materials

29. Penetrance

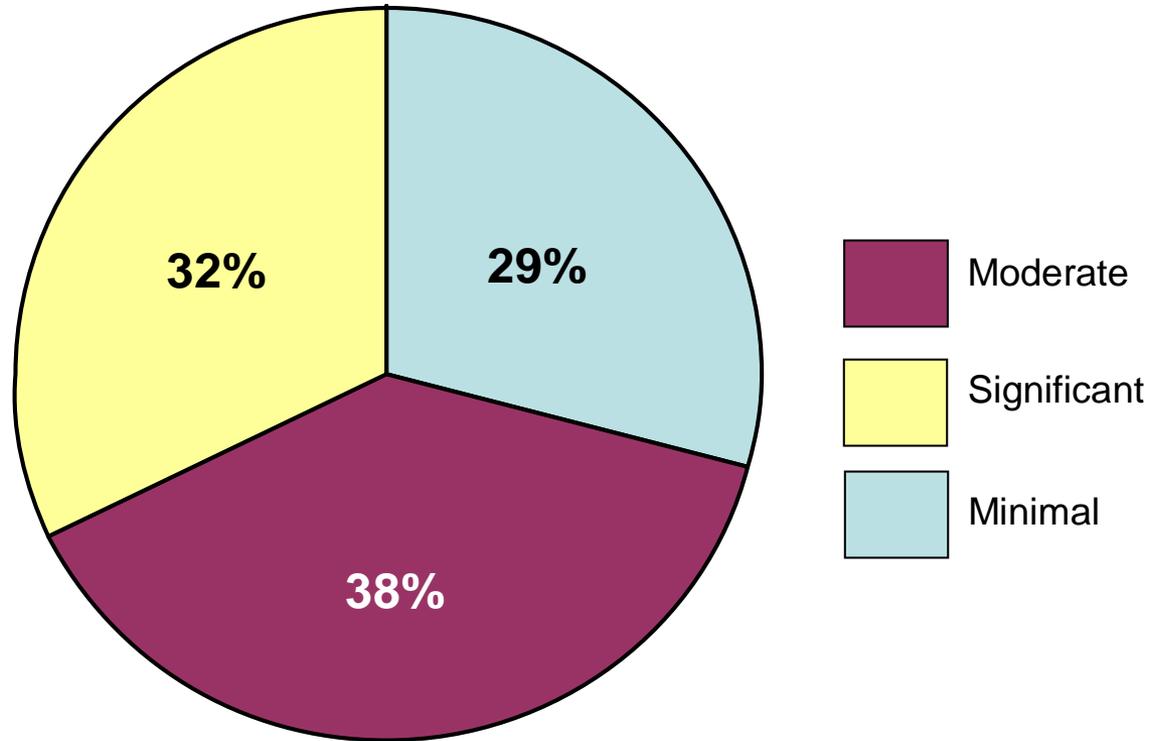
30. Cost

31. Validation reports

32. Other

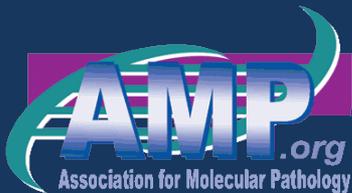
33. Modifiers

If the GTR were somehow made mandatory, what would be the impact on your laboratory?



Mandatory?

- 12% would stop providing testing
- AMP members are international
 - Outside US, less interest in participating in NIH's GTR



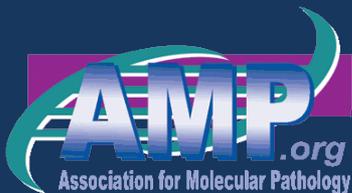
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AMP's GTR survey - concerns

- Increased burden for laboratories to maintain up-to-date information
- How information would be used by
 - Competitors
 - Payers
 - Regulators
- Lack of curation
 - How accurate would be the data?



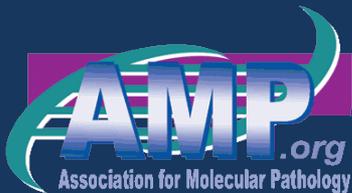
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AMP's GTR survey – concerns 2

- Disclosure of proprietary information
- Purpose as defined in the RFI was unclear
 - NIH involvement in clinical activities
 - How GeneTests will be affected?
- With potential FDA oversight of LDTs, how will the GTR relate to the FDA?



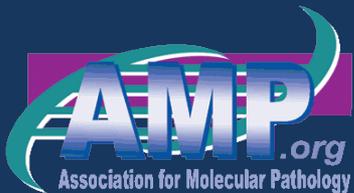
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AMP's response to Public Meeting

- Held in conjunction with ASHG 2 Nov. 2010



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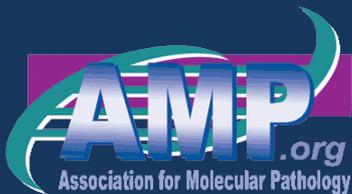
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1. What criteria should be used to determine which genetic tests should be included in the first phase of the GTR, and what types of tests would meet these criteria?

Intent to facilitate research

- New clinical tests translated from GWAS studies
- Pharmacogenomics
- Tests offered from sole source providers.



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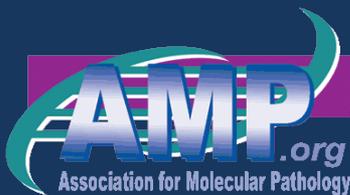
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2. Given that data submitters are unlikely to have clinical utility information, how is this data element best addressed in the GTR?

- Clinical utility should be provided by experts in the field and professional societies (AMP, ACMG, ASCO), and CDC's EGAPP, ARHQ reviews.
- GeneReviews format would be accessed and readable.
- Orphanet includes clinical utility summary reports (<http://www.orpha.net/consor/cgi-bin/home.php?Lng=GB>).

For tests with similar types of results, the clinical utility should be addressed in a centralized manner rather than individual submissions.



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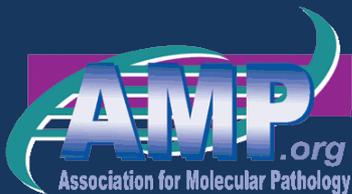
3. What are the benefits, risks, and challenges of including cost information in the GTR?

Cost and price are two different issues

Costs

- Price of reagents
- Labor (geographical variations)
- Royalties
- Equipment depreciation
- Overhead
- Other expenses

Most respondents consider cost to be confidential information.



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3. What are the benefits, risks, and challenges of including cost information in the GTR? (continued)

Price

- Contracts with various payers
- Negotiated price is separate from the list price.
- Federal fee schedule by CPT codes.

In our survey 52% of respondents would provide CPT codes.

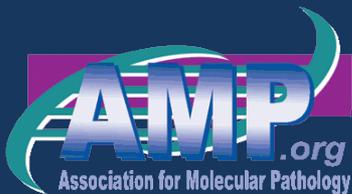
NIH should respect the user's right to withhold cost and price information. This is essential to the GTR's credibility.

4. What safeguards can be put in place to prevent GTR users from misunderstanding, misinterpreting, or misusing the information in the Registry?

- Definitions
- Hyperlinks to other sources of information

Proprietary information should not be included in the GTR.

The GTR will be most useful if it remains a scientific resource.



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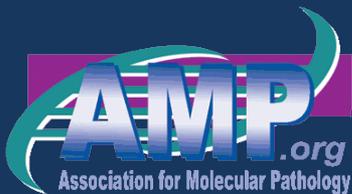
5. What mechanisms can be used to provide materials that explain the GTR's data elements to audiences with varying technical expertise?

From our survey

- 88% indicated that resource for healthcare providers and other laboratories
- 50% for genetic research

The design (elements, approach and format) of a registry for diagnostic or treatment data will differ from a registry for genetic research or public education.

Can this be achieved within a single product?

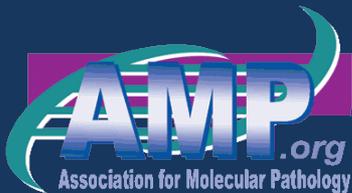


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Thank you for responding to
the AMP survey



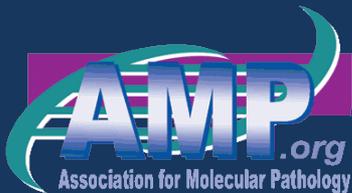
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