Healthcare Professionals’ Perspectives:
FDA Proposed Rule on Generic Drug Labeling
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Background

- In November 2013, the FDA issued a proposed rule on labeling for approved medicines known as the Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products. This rule would permit generic drug manufacturers to modify their safety labels when they receive new safety-related information specific to their drug in advance of FDA review. Among potential issues, this ruling could result in multiple different safety labels being in the market for the same drug.

- The intention of this study was to ascertain the awareness of physicians, pharmacists and physician assistants of this proposed rule, and their perceptions of how it may impact them and/or their patients.
Methodology

• PublicMind conducted a nationwide random telephone survey of 450 physicians, physician assistants and pharmacists on behalf of GPhA. The survey instrument was pre-tested with a small group of respondents prior to launching the full study. The sample was randomly generated from several list sources. Once the sample was received by PublicMind, the contacts were randomized and called. As many as 10 calls were attempted before the contact was considered exhausted.

• The telephone interviews were conducted from March 24th through April 11th, 2014 using a randomly selected sample of physicians, physicians assistants, and pharmacists. In all, 450 surveys were completed; 150 among each group. All interviews were conducted by OpinionAmerica Group, Inc. of Cedar Knolls, NJ by professionally trained interviewers using a CATI (Computer Assisted Telephone Interviewing) system.

• PublicMind staff oversaw all aspects of the survey –questionnaire design and approval, timing, staff training, data collection and analysis.
Conclusions

• Among those surveyed, there is a strong belief (86%) that the current information available about the safety of generic drugs is adequate.

• News of the proposed new generic drug labeling rule has not yet reached physicians, pharmacists or physician assistants; in fact 79 percent say they have heard ‘nothing’ about this rule.

• Prescribers and dispensers both expressed the belief that the proposed new rule would lead to confusion in the marketplace. Most (76%) say their patients would be at least somewhat confused, while more than half (53%) say having multiple safety labels would be ‘very’ confusing for themselves.

• Most believe the new rule would have a negative impact on their time.
  – 71% anticipate the new rule would increase the amount of time they need to spend with their patients reviewing patient history and the new labels; and
  – 74% percent believe it would have at least some impact on the time they will need to spend researching labeling differences.

• Equally as important, most (68%) believe they would NOT have the time required to keep current with the labeling changes.
Conclusions (con’t)

• The majority (81%) believe FDA approval should be required prior to changing generic safety labels; while almost all (90%) believe access to safety data should be required prior to changing generic product safety labels.

• Concerns regarding liabilities are also an issue, as 77 percent are at least somewhat concerned the proposed new rule could impact their legal liabilities. This concern is even more pronounced among pharmacists (85%).

• 60 percent say the proposed rule would have at least ‘some’ impact on their willingness to prescribe generic drugs in the future.
Detailed Findings
Is Current Information on the Safety of Generic Drugs Adequate

Overall, most (86%) believe the current information they receive about generic drugs is adequate. Differences exist between physicians, physician’s assistants and pharmacists. In addition, those in title for 10 or fewer years (93%) are more likely than those with 10+ years (84%) to say the information is adequate.
Most (79%) say they are totally unaware of the proposed new ruling. Physicians (86%) are more likely than physicians assistants (77%) or pharmacists (73%) to have heard nothing at all.
Overall, 4 in 5 (81%) say FDA approval should be required before any safety label information is changed. No significant differences exist across any demographic.
More than 1 in 3 (34%) say the potential for multiple warning labels will have a great impact on patient confusion. An additional 42 percent say it will have at least some impact, while only about 1 in 5 (22%) say it will not have any impact on patient confusion. More women (40%) than men (30%) say it will have a great impact. Those who do not think the currently available information is adequate are more likely (50%) to say the proposed rule will have a great impact.
Impact on Time with Patients

Seven in 10 (71%) believe the proposed new rule will have at least some impact on how much time they need to spend with patients cross referencing their history with various labeling differences. No differences exist across respondent type, although men (31%) are more likely than women (19%) to say the rule will have no impact.
Nearly 3 in 4 (74%) believe the new rule will have some (51%) or a great impact (23%) on the time they need to spend researching labeling differences. Fewer than 1 in 4 (22%) say it will have no impact. Physician assistants (17%) are less likely than the others to say it will have a great impact. Those who believe the current information is not adequate are more likely than those who believe it is adequate to say it will have a great impact on their time.
Nearly 9 in 10 (88%) say having multiple labels for similar drugs would be very (53%) or somewhat (35%) confusing for them. Only 1 in 10 (12%) say it would not be confusing. Time in title plays a significant role on the responses.
Nearly 7 in 10 (68%) say they are either not very (34%) or not at all (34%) likely to have the necessary time to keep up with labeling changes. Only 1 in 10 (11%) say it is very likely they will have the time.
Forty two percent say they would be concerned a lot that different safety warning labels could impact their legal liabilities. Only 10 percent would not be concerned at all. Pharmacists (53%) are most likely to say they would be concerned a lot.
Impact on Recommending Generic Drugs

Overall, 3 in 5 (60%) say the proposed rule change would have a slight (41%) or great (19%) impact on their willingness to recommend generic drugs. More physicians (23%) than physician assistants (14%) say their willingness would be greatly impacted. Pharmacists were not asked this question.
Should Access to Safety Data be Required for Label Changes

The vast majority (90%) believe access to safety data should be required prior to changing generic product safety labels. More pharmacists (93%) than physicians (85%) say it should be required, while more physicians (10%) are unsure.
Most (96%) physicians in the study have been physicians for 10 or more years. Conversely, only about half (55%) of the pharmacists have been in title for 10 or more years. The chart on the left shows the detailed breakdown of time in title, while the one on the right shows the years grouped to under or over 10 years.
More physicians in this study were men (81%) than women (19%). More physicians assistants were female (55%) than male (45%), while pharmacists were just the opposite, with 55 percent being men and 45 percent women.

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<th>Sample Size</th>
<th>Total</th>
<th>Time in Title</th>
<th>How Much Heard of Rule</th>
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