

### Background

The Food and Drug Administration (FDA) recently published The Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling, referred to as the "Pregnancy and Lactation Labeling Rule" (PLLR).<sup>1</sup> In 1979, the FDA categorized the risks of taking a drug or biological product during pregnancy under a five-letter system (A, B, C, D and X), often misinterpreted as a grading system.<sup>2</sup> Drugs in category A are deemed as well studied and safe in the first trimester of pregnancy, in comparison to drugs in category X, that are teratogenic and contraindicated in pregnancy. Drugs in category B, C, and D warrant the healthcare provider to weigh the risks and benefits of prescribing. With this pregnancy label update, drug manufacturers are required to provide specific details pertaining to its use in pregnancy, lactation, and reproductive risks associated with the drug's use. The labeling directs women to pregnancy registries that have been established for specific drugs, with changes to their labeling, and includes information about the need for pregnancy testing, contraception recommendations, and information about infertility as it relates to the drug.<sup>3</sup> The purpose of our study was to better gauge pharmacists' awareness and understanding of the impact and use with regards to the pregnancy labeling updates.

### Objective

To identify the knowledge gap amongst pharmacists, as well as, their understanding of the changes that may arise from the new pregnancy labeling updates.

### Method

To assess the impact of the pregnancy labeling update, an electronic survey was delivered via email to professionals who currently serve as community pharmacists and clinical/staff pharmacists in the EMSOP experiential program. This comprehensive survey will be used to collect information on the specific challenges pharmacists are facing (i.e. lack of knowledge, greater volume of patient inquiries, increase in communication with HCPs). This study was approved by the Rutgers e-IRB.

### Disclosure

Author(s) of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

- Galina Perel: Nothing to Disclose
- Gunjan Patel: Nothing to Disclose
- Michael Toscani: Nothing to Disclose
- Donna M. Feudo: Nothing to Disclose

### Results

Upon review of the data collected from the distribution of our survey, a total of 119 responses were received from pharmacists who currently work in community and clinical settings in New Jersey. These were submitted and analyzed for results. Of the 119 surveys analyzed, 74 stated they are aware of the updated pregnancy labeling updates. In comparison of those surveyed, only 14 individuals reported that their physicians are aware of the updates through daily interdisciplinary interactions (**Figure 1**).

Figure 1: Knowledge Gap in Pregnancy Labeling Updates

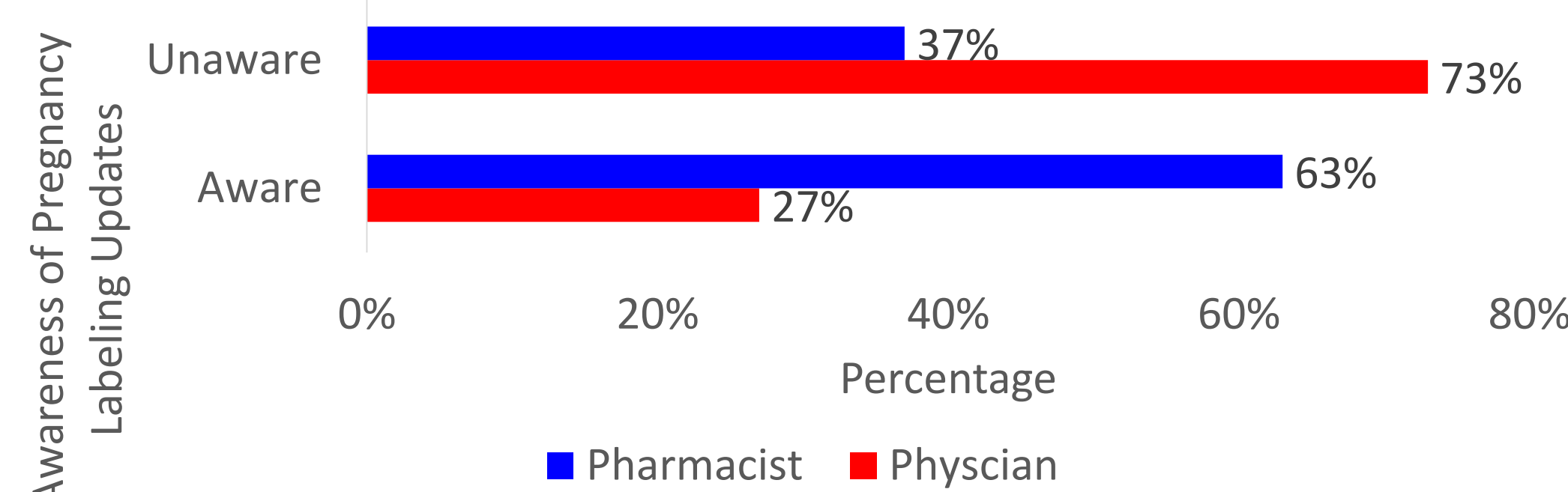
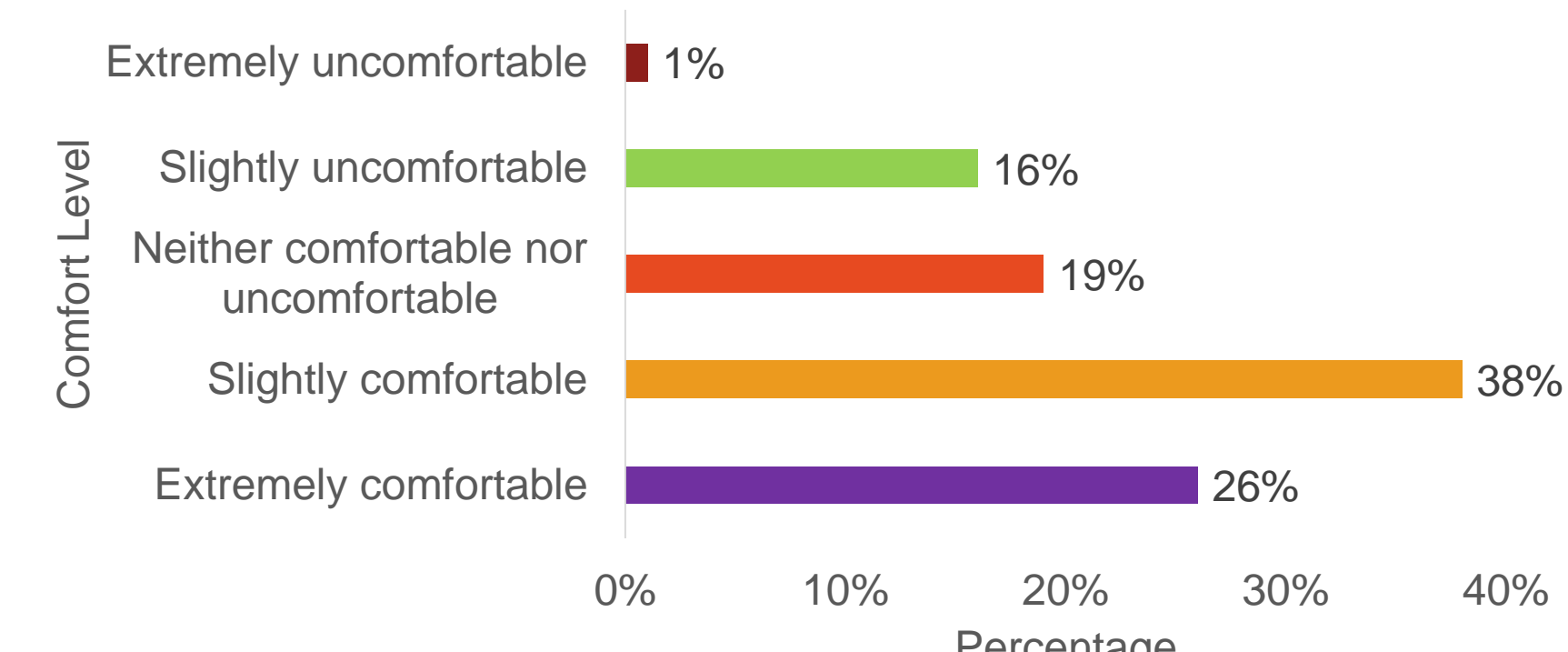


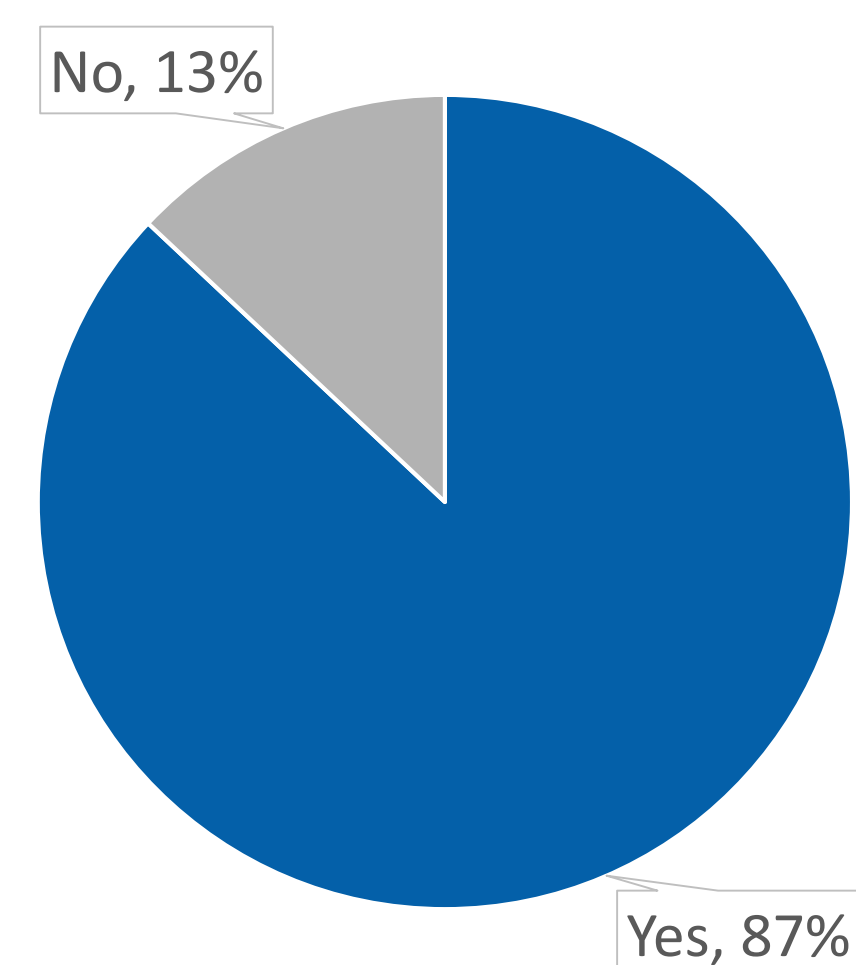
Figure 2: How comfortable are you with identifying any potential contraindications or interactions and dispensing medications to pregnant patients?



Note: Percentage based off of total number of responses (98). Survey participants were allowed to pick more than one answer. Not all respondents completed this question.

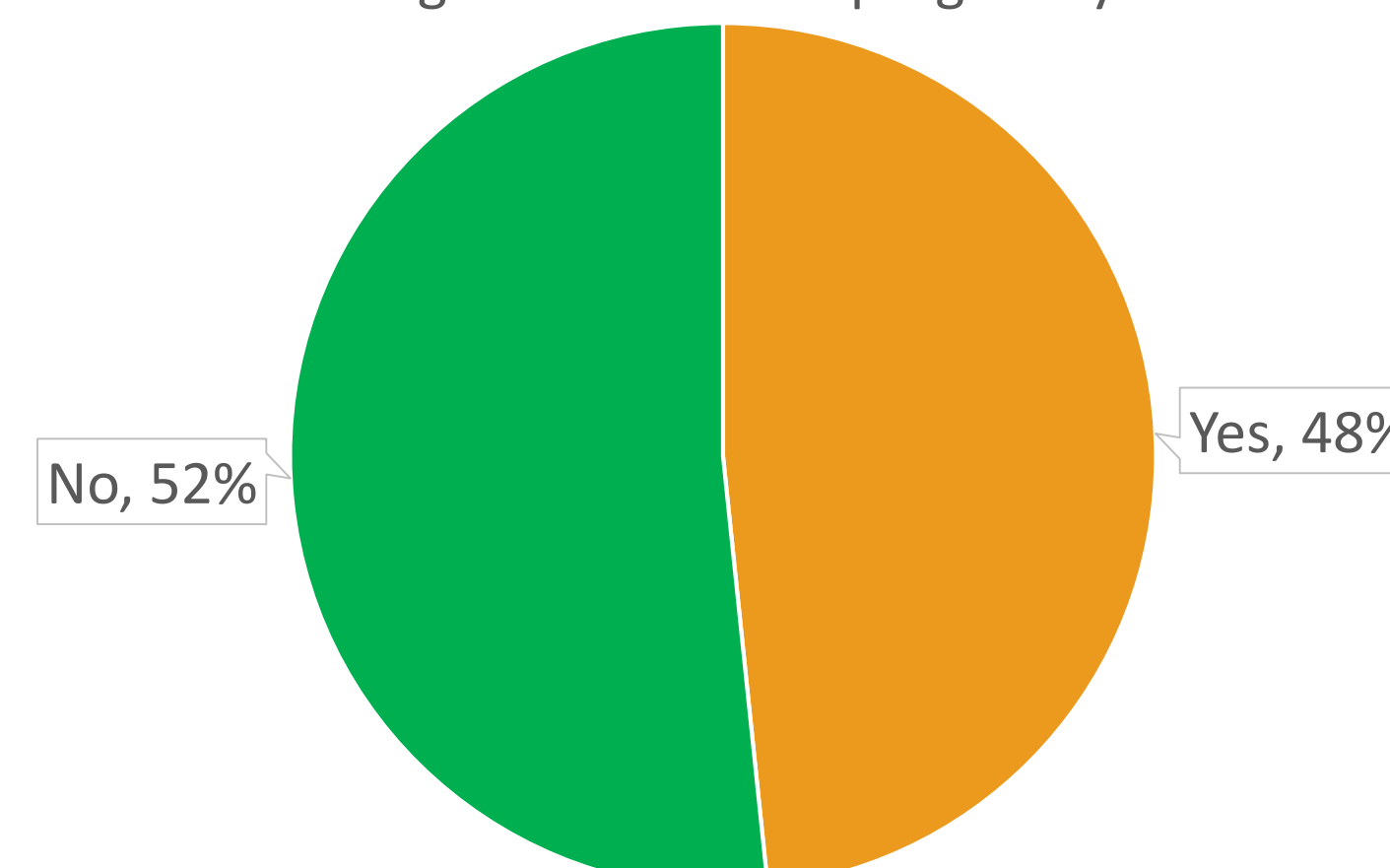
Of those surveyed, 26% reported that they are extremely comfortable and 38% stated they are slightly comfortable with identifying any potential contraindications or interactions when dispensing medications to pregnant patients (**Figure 2**). Based on responses collated, there is an identified educational gap in 37% of pharmacists' when dispensing medications. In supplement to the understanding and awareness gap, our results indicated that 87% of pharmacists' need additional training on the new pregnancy categories and label updates (**Figure 3**).

Figure 3: Do you feel that you need more training on the new pregnancy categories?



Note: Percentage based off of total number of responses (92). Survey participants were allowed to pick more than one answer. Not all respondents completed this question.

Figure 4: Do you see an increase in patient awareness and questions pertaining to the effects of drug before or after pregnancy?

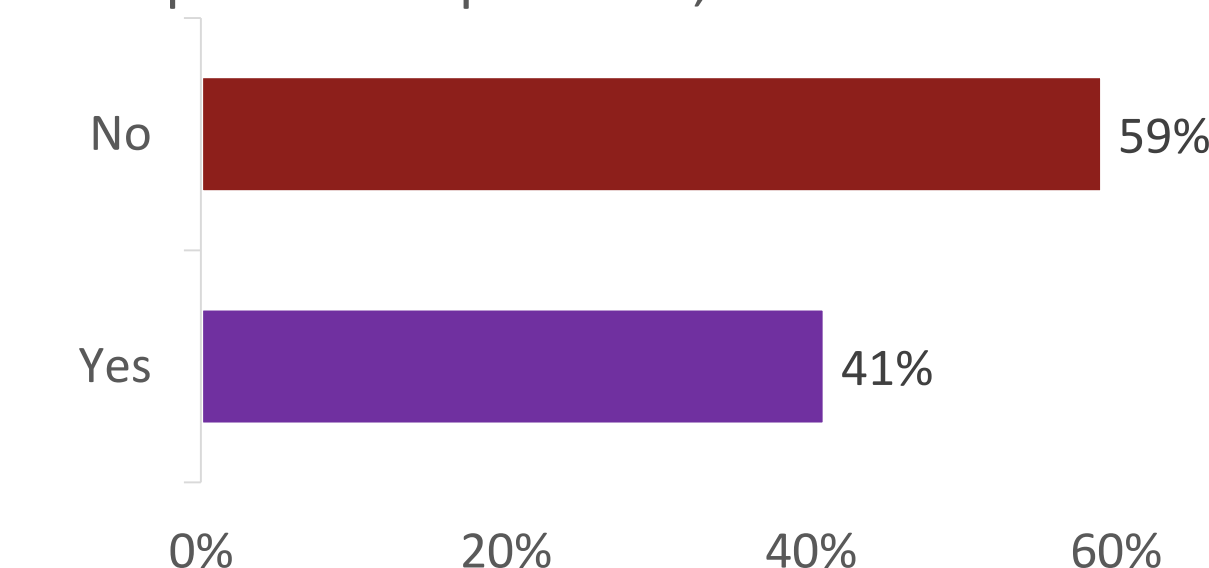


Note: Percentage based off of total number of responses (91). Survey participants were allowed to pick more than one answer. Not all respondents completed this question.

### Results/Discussion

In addition to the educational gap assessment, our results indicated that 52% of pharmacists' have not observed an increase in patients' awareness and questions pertaining to the effects of prescription medication use before or after pregnancy. On average, less than 50% of pregnant patients are inquiring for information about the effects of exposure of prescription medications before and during pregnancy (**Figure 4**). Pharmacists can have a significant and positive impact on patient care and therapeutic outcomes through effective counseling. By providing the necessary education to patients when dispensing prescription medications, pharmacists' have an opportunity to identify any potential medication errors. Our results demonstrated that the pregnancy label updates have resulted in an increase in counseling in 41% patients of reproductive potential, both male and female (**Figure 5**).

Figure 5: Have these changes caused an increase in counseling for patients of reproductive potential, both male and female?



Note: Percentage based off of total number of responses (88). Survey participants were allowed to pick more than one answer. Not all respondents completed this question.

### Conclusions

After an assessment of the updated pregnancy labeling rule and its impact on the pharmacists studied here, it can be concluded there is an educational gap with a need to increase healthcare professionals' interdisciplinary comprehension of the new labeling pregnancy rule. With appropriate and up to date counseling, pregnant patients at the time of counseling have shown potential comprehension and patient satisfaction.

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### References

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