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## Background

- Pharmaceutical companies provide medical information in response to healthcare provider inquiries through various channels, namely written standard response letters.
- The U.S. Food and Drug Administration (FDA) provides some guidance on standards for responding to unsolicited requests.<sup>1</sup>
- The FDA Draft Guidance provides the following standards: information distributed in response to an unsolicited request should be provided only to the individual making the request; the information should be tailored to answer only the specific question; information should be truthful, non-misleading, accurate, and balanced; information should be scientific and generated by medical or scientific personnel; and specific information needs to accompany the distribution of the unsolicited request.<sup>1</sup>
- The Draft Guidance is not very clear on the specifics of these requirements and how standard responses can be structured to account for all of these factors.<sup>1</sup>

## Objective

- To identify how pharmaceutical companies structure their medical information standard responses globally to communicate relevant information to healthcare providers.
- To compare the structure of medical information standard responses in the U.S. versus in Europe.
- This data can be used to develop best practices of how information is effectively communicated to healthcare providers and create clarity on how select pharmaceutical companies provide answers to healthcare providers focusing on the structure of the responses.

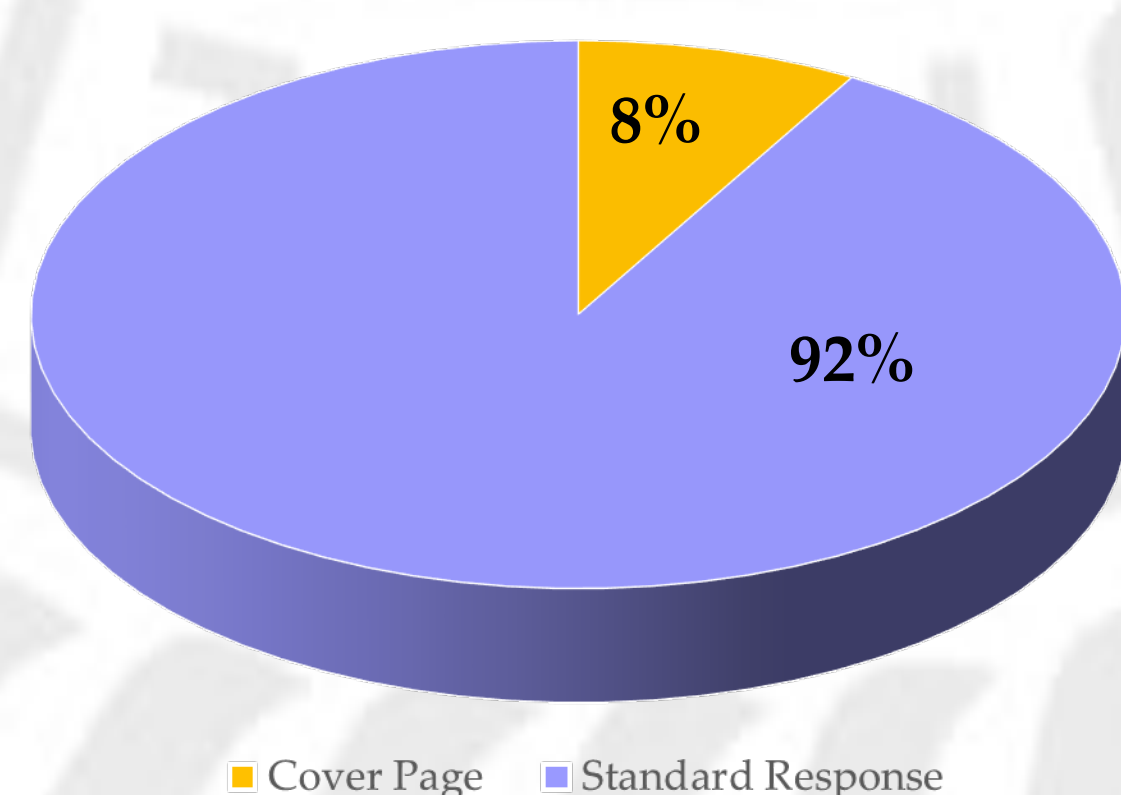
## Methods

- This research was approved by the Rutgers Institutional Review Board.
- This research was completed in two phases:
  - ❖ There were two separate open-label, prospective, anonymous surveys distributed to 25 pharmaceutical companies through an online survey tool.
  - ❖ Each survey contained 10 questions.
  - ❖ The **first survey** evaluated medical information standard response structure in the U.S.
  - ❖ The **second survey** evaluated medical information standard response structure in Europe.
- Factors evaluated and answered through the survey include:
  - ❖ Location of the answer (immediately on the cover page or in the body of the standard response)
  - ❖ Length of standard response (1-2 pages, 3-5 pages, 5-10 pages, > 10 pages)
  - ❖ Inclusion of prominent safety information (direct lift from the prescribing information, reference to the prescribing information, inclusion of a hyperlink)
  - ❖ Inclusion of approved product indications (direct lift from the prescribing information, reference to the prescribing information, inclusion of a hyperlink).

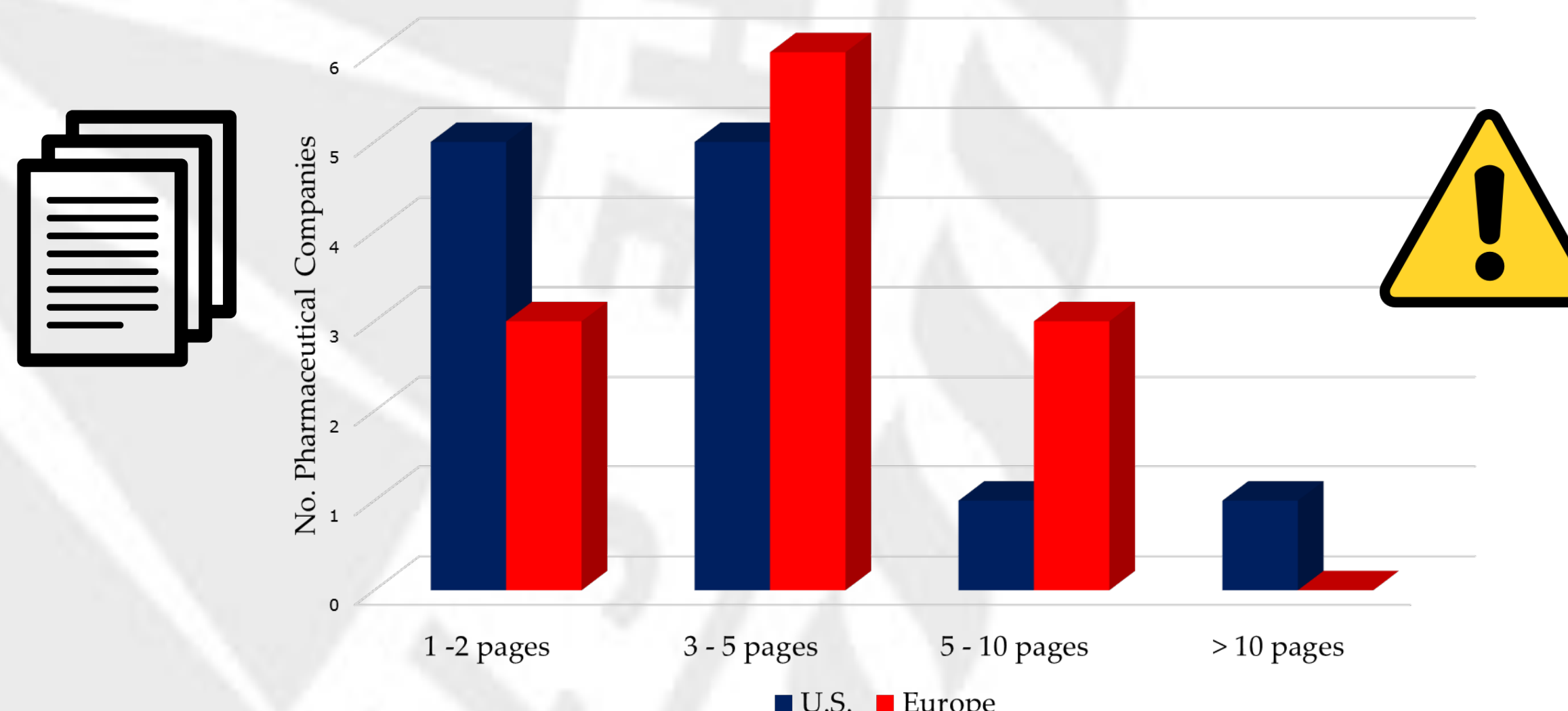
## Results

- Of the 25 pharmaceutical companies evaluated in both phases, responses were received from 12 companies in each phase.
- Based on survey results, the answer to the inquiry can be found predominantly in the standard response (92%) and the cover page (8%) in Europe, (**Figure 1**) versus in the standard response (83%) and the cover page (17%) in the U.S.
- The average length of a single standard response is predominantly 3 – 5 pages (50%) in Europe versus 1 -2 pages (42%) and 3 – 5 pages (42%) in the U.S., **Figure 2**.
- There are various sections contained within the cover letter, **Figure 3**:
  - ❖ **Responses in Europe:** Product indications (33%), boxed warning (33%), important safety information and warnings (60%), and prescribing information hyperlink (20%).
  - ❖ **Responses in the U.S.:** Product indications (58%), boxed warning (42%), important safety information and warnings (50%), and prescribing information hyperlink (33%).
- Safety information is predominantly found as a direct lift in the standard response in both Europe (83%) and the U.S. (33%), **Figure 4**.
- Approved indications in a standard response can be found primarily as a direct lift in the standard response package in Europe (67%) versus on the cover page in the U.S. (42%), **Figure 5**.

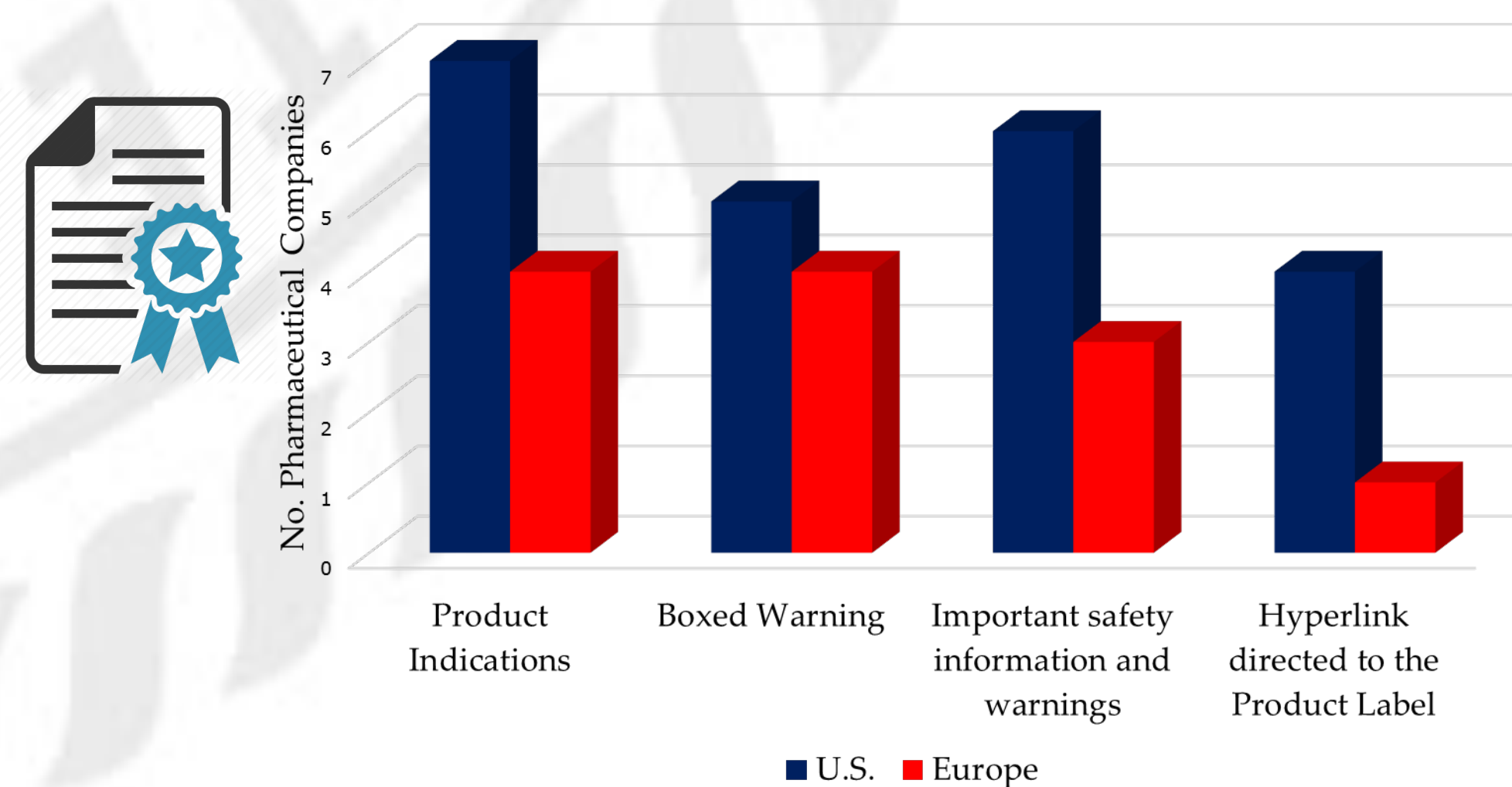
**Figure 1. Location of the Answer in the Standard Response Package in Europe**



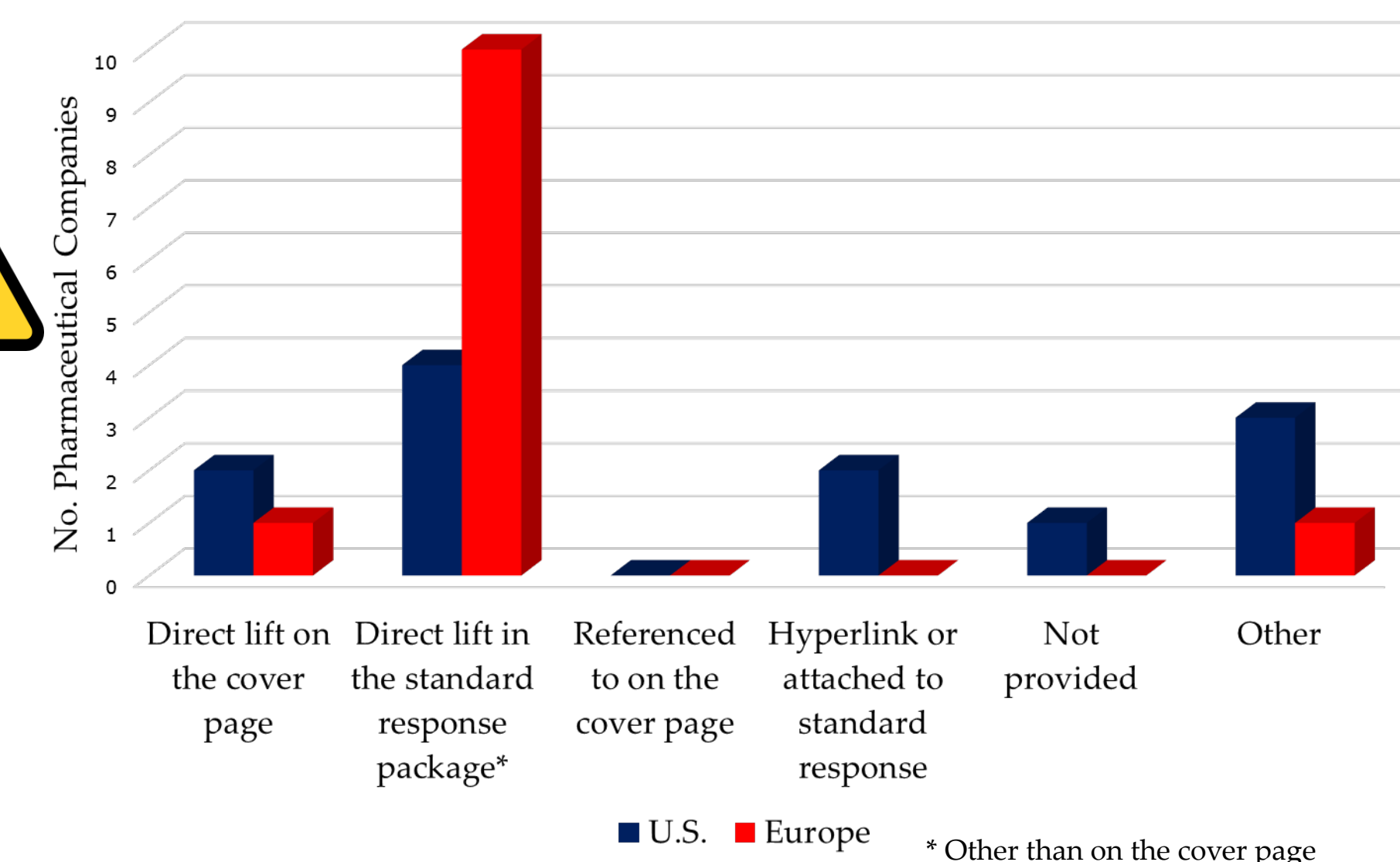
**Figure 2. Average Length of a Standard Response to a Single Inquiry**



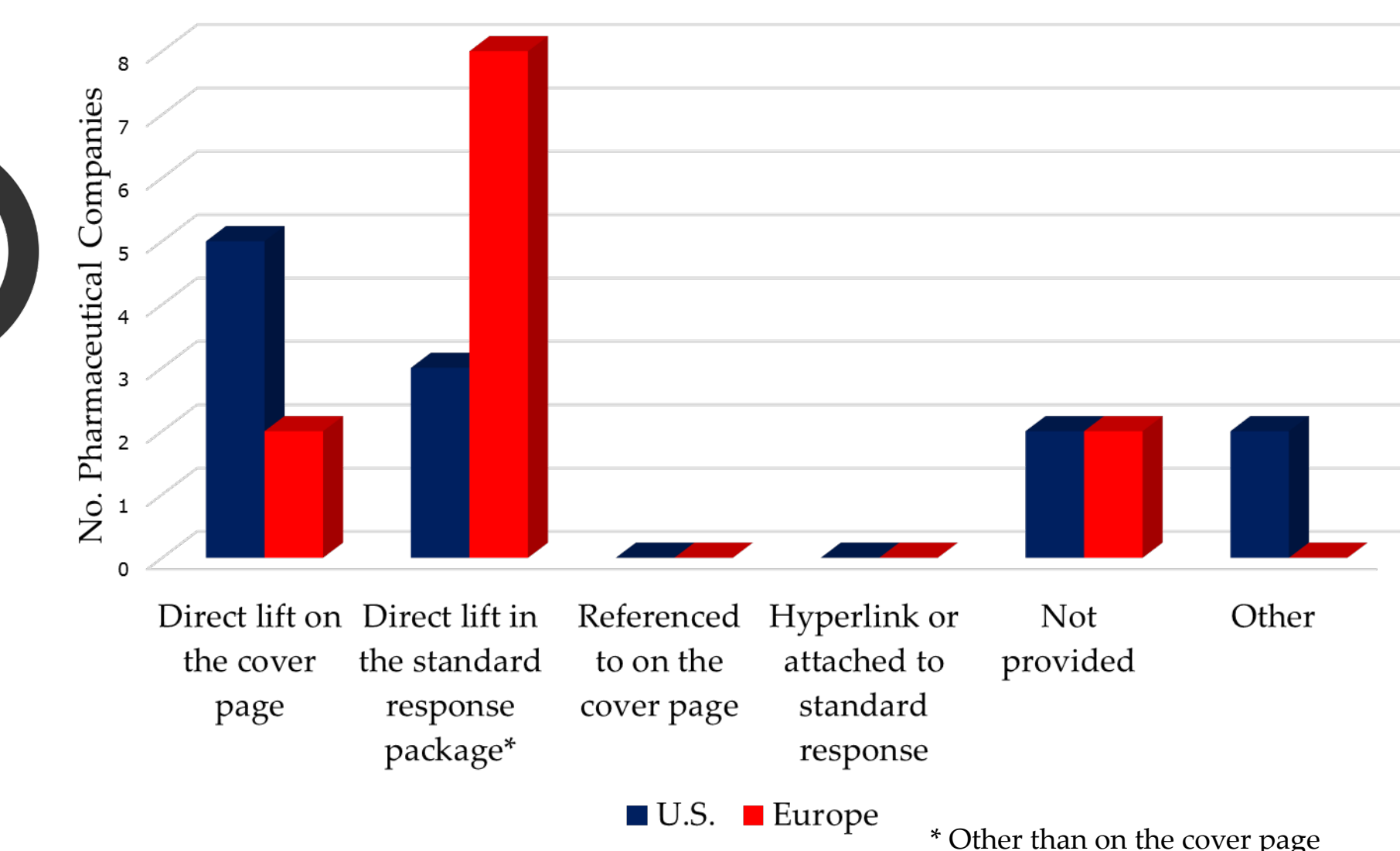
**Figure 3. Relevant Sections Contained in the Cover Letter**



**Figure 4. Location of Safety Information in a Standard Response**



**Figure 5. Location of Approved Indications in a Standard Response**



## Discussion and Limitations

- Of the 25 pharmaceutical companies evaluated across both phases, there were 12 responses received in each phase.
- The results of both phases of this research varied across each of the 12 pharmaceutical companies that responded to either survey providing a comparison of the structure for medical information standard responses in both Europe and the U.S.
- Among the companies surveyed, the answer to the inquiry can be found predominantly in the standard responses (92% and 83%) versus the cover page (8% and 17%) in both Europe and the U.S., respectively.
- Across European and U.S. medical information standard responses, the average length of a response to a single inquiry falls less than 5 pages for the majority of companies surveyed. However, responses > 10 pages were identified in 0% versus 8% of companies surveyed in Europe and the U.S., respectively.
- Safety information in medical information standard responses is predominantly found as a direct lift in the standard response in Europe (83%) and in the U.S. (33%). Although this represents the majority of companies surveyed, there is a large disparity between the amount of pharmaceutical companies that provide the safety information as a direct lift in the standard response across both Europe and the U.S.
- Product indications are found primarily in the standard response package in Europe versus in the cover page in the U.S.
- A limitation of this study included the number of pharmaceutical companies sampled. A greater sample of pharmaceutical companies could have been surveyed to achieve a more diverse sample.
- An additional limitation of this study included the subjectivity of the questions included in the survey. A more qualitative assessment of the medical information standard responses globally can be done to evaluate the structure of medical information standard responses to aid in better understanding any differences.

## Conclusions

- Results of this research indicate there is no consistent structure of medical information standard responses utilized across pharmaceutical companies. However, there are some commonalities including maintaining the standard response to < 5 pages thus providing a concise response to consumer inquiries.
- The implications of the results are to begin establishing more clear guidance around a consistent medical information standard response structure that aims to be scientific, accurate, fair, and balanced, and ultimately, meets the needs of the customer.

## Disclosures

- Rebecca Weingard, CSSBB is an employee of Bristol-Myers Squibb.

## References

1. Food and Drug Administration. Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices. Updated: December 2011. Available at: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf>. Accessed 20 February 2015.
2. Bundra K, Hermes-DeSantis E, Sheng I. Analysis of Medical Information Standard Response Structure across Pharmaceutical Companies. Presented: March 17, 2015; DIA Medical and Scientific Communications Annual Forum 2015: Glendale, AZ.

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