# RUTGERS Ernest Mario School of Pharmacy

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## Background

The Medical Information (MI) department in a pharmaceutical company is generally responsible for writing responses to unsolicited requests from Healthcare Providers (HCPs) and collaborating with Medical Science Liaisons (MSLs) in real-time customer engagement. Standard Response Document (SRD) creation and maintenance is an ongoing task that ensures responses to HCPs include up-to-date clinical data. As a company's drug portfolio expands, mature lifecycle products may have a lower priority and less MI support and visibility. This project seeks to evaluate the current practices of MI departments for their mature brands (legacy products) and the amount of support given towards these products.

## Objective

To identify similarities and differences in which medical information departments currently answer unsolicited requests on mature products and manage their MI databases to include up-to-date clinical data.

## Methods

To assess the management of SRD databases, an electronic survey was delivered via email to target professionals who are currently employed in U.S. MI departments at top pharmaceutical companies based on 2016 global sales. A survey was used to collect information on the overall practices within their department without specifically targeting a specific company, product, or process. Results were compiled to identify commonalities and gaps within practice that can be improved upon as an industry.

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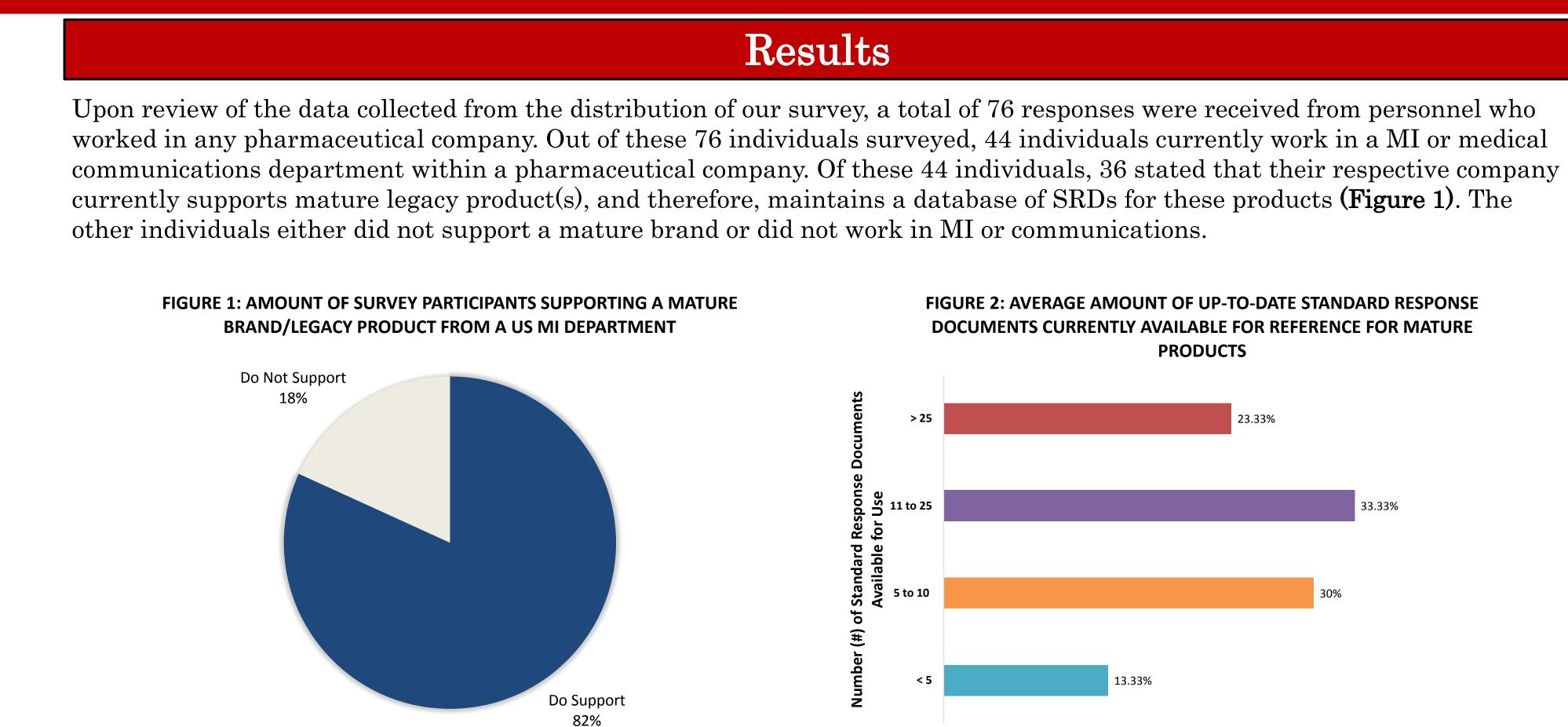
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## Disclosure

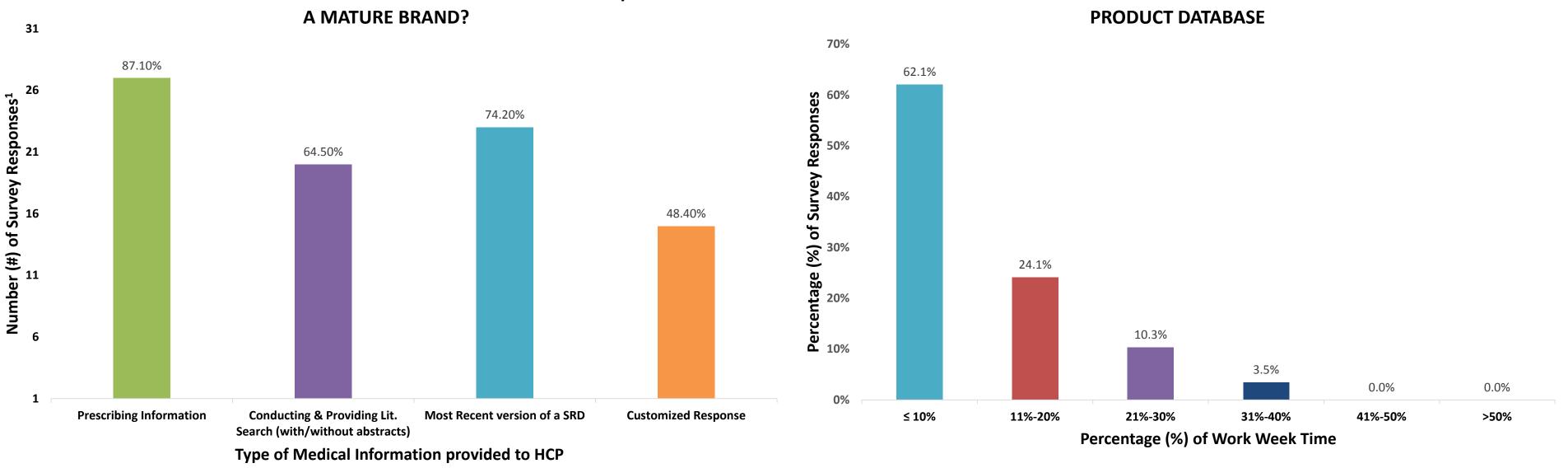
Author(s) of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

- Corey Fang: Nothing to Disclose
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## Assessment of Standard Response Database Management for Mature Brands by U.S. Medical **Information Departments of Pharmaceutical Manufacturers**



Of those surveyed, 63.3% reported that for the mature products in their portfolio, the number of active SRDs retained within their database ranged from 5-25 responses (Figure 2). Based on responses for actively promoted products, the amount of active SRDs generally ranged from less than 25 to greater than 100. In comparison to actively promoted products, our results indicate that the process for updating SRDs for mature products differs in that there is less periodic review, content updating timelines become less stringent, and a more reactive approach is used versus a proactive approach when updating SRD content.



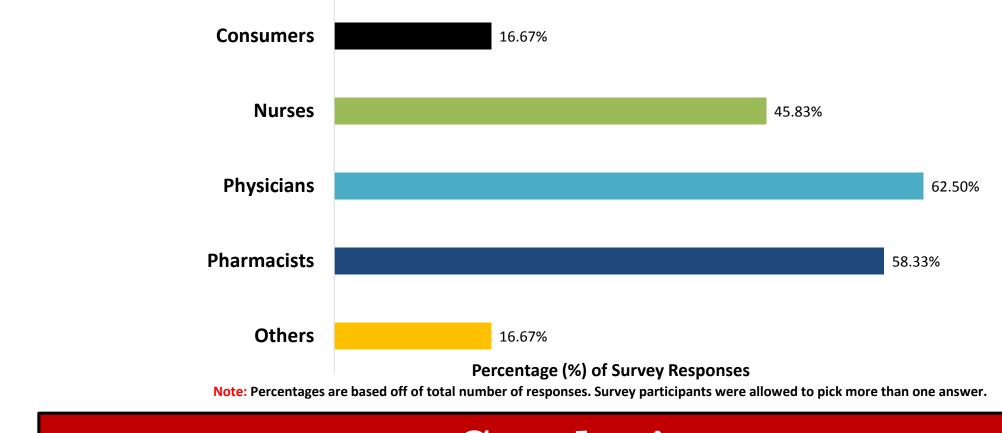
: Percentage based off of total number of responses (31). Survey participants were allowed to pick more than one answer Not all respondents completed this question.

FIGURE 3: WHAT INFORMATION IS PROVIDED TO THE CONSUMER/HCP FOR

Percentage (%) of Survey Responses



The majority of medical information requests for mature products are submitted by physicians, pharmacists, and nurses alike (Figure 5). The MI department specialists refer the HCPs to the products package insert to address their specific question 87% of the time. In addition to the product's package insert, survey results indicated that the most up-to-date version of a SRD or information gathered from a customized literature search are viable sources used to address questions for mature products. Dissemination of the most up-to-date version of a SRD was done 74% of the time, while customized literature search results were disseminated 48% of the time. The amount of time dedicated to updating and maintaining a database for mature products, 62% of survey participants claim to only spend approximately 10% of their time on their mature brands. Results also show that efficiencies have already been made on the following matter and are further discussed in the Conclusions section.



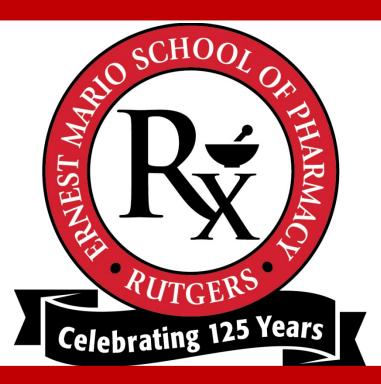
As a company's overall drug portfolio expands, it can be concluded that mature lifecycle products become a lower priority than actively promoted brands, and thus, are provided less support by the MI/Communications departments.

Actively promoted brands generally have 51-100 SRDs which are proactively updated, in contrast to a mature brand that may only have 11-25 SRDs reactively updated. Important considerations for the number of up-to-date mature brand SRDs include the amount of time (in years) that the mature drug has been used in clinical practice which may increase HCP familiarity with the product and decrease the number of clinical questions they have. These factors can impact the amount of inquiries and consequently the number of SRDs necessary to maintain up-to-date in a database. This reactive update and review process is not common to all pharmaceutical companies as some companies will stop updating their mature brand SRDs due to lack of MI support regardless of the number of inquiries and only provide the latest version with the date of last review.

Our results indicate that the product's package insert is predominantly provided to address questions submitted by healthcare professionals for mature brands, in many cases customized literature searches were conducted and responses were created to address product specific questions (Figure 3).

Although, workweek time usage seemed to be minimally impacted by these products (Figure 4). When prompted about current practices, 70% of participants believed their current practices for updating a mature brand SRD was adequate. Efficiencies brought up by survey participants included reflecting mature brand support in workweek time allocation, training call center to answer questions without escalation and removing prescribing information as any FDA updates may incur more revision time.

We can conclude from these results that more time allocated to updating and maintaining the SRD databases for mature brands can prove to be beneficial, as it could potentially decrease the need and time allocated to customize literature searches and responses to address questions.



### **Results** (continued)



### Conclusions