Background
As technology advances and mobile platforms become more user-friendly, the mobile application market grows in every industry, including pharmaceuticals. With the availability of applications, millions of patients seek assistance with the multitude of assisting patients with their health and wellness management. These mobile applications can range from having basic functions, such as keeping track of health records, to qualifying as an FDA approved medical device. FDA regulations on applications as medical devices if they meet the definition of a device and one of the three predetermined functionalities. These applications would not be included in the FDA oversight, as they are not intended for use by patients and therefore may not be relevant to include in the analysis.

The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis. The two Roche Accu-Chek applications work only as accessories to the already regulated INRange/Vantus meter and are not intended to diagnose, cure, mitigate, treat, or prevent disease. The three top pharmaceutical companies, by 2018 revenue, Pfizer, Roche, and Sanofi were included for the descriptive analysis. The applications were reviewed to determine which, if any, criteria were met on the checklist. The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis. The two Roche Accu-Chek applications work only as accessories to the already regulated INRange/Vantus meter and are not intended to diagnose, cure, mitigate, treat, or prevent disease. The three top pharmaceutical companies, by 2018 revenue, Pfizer, Roche, and Sanofi were included for the descriptive analysis. The applications were reviewed to determine which, if any, criteria were met on the checklist.

Method
The top three pharmaceutical companies, by 2018 revenue, Pfizer, Roche, and Sanofi were selected for this descriptive analysis.2 The available applications for these companies were surveyed through the descriptions posted in the Apple App Store and Android Play. Furthermore, many applications available and which the FDA may focus their regulations on, there were some existing regulated medical devices that were reviewed, but did not meet the criteria for an FDA regulated mobile medical application. The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis. The two Roche Accu-Chek applications work only as accessories to the already regulated INRange/Vantus meter and are not intended to diagnose, cure, mitigate, treat, or prevent disease. The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis. The two Roche Accu-Chek applications work only as accessories to the already regulated INRange/Vantus meter and are not intended to diagnose, cure, mitigate, treat, or prevent disease.

Objective
The primary objective is to evaluate existing patient-focused mobile application functionalities according to the Mobile Medical Applications FDA Guidance, released in 2015, in order to assess the existing gaps and consider the potential industry ramifications on registering mobile applications as medical devices.

Results
Mobile Applications

<table>
<thead>
<tr>
<th>Company</th>
<th>Diagnosis</th>
<th>Cure</th>
<th>Mitigation</th>
<th>Treatment</th>
<th>Prevention</th>
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<tbody>
<tr>
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<tr>
<td>Sanofi</td>
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Conclusions
There are more medical focused applications developed by pharmaceutical companies available, which allow patients to be more knowledgeable and active in their treatment decisions. With this growth, also comes the potential for risk if the applications do not function as intended. The FDA currently focuses their oversight on a particular subset of criteria, which the majority of available mobile applications do not meet. Applications, which meet the parameters outlined by the FDA, are required to register as a medical device. These medical devices also have the potential to provide industry with additional patient monitoring information for postmarketing surveillance, such as risk evaluation and mitigation strategies (REMS), and real world data with patient-reported outcomes. Our goal was to better understand how the current mobile applications market fits into the FDA Guidance outlined criteria for regulation. It is not yet fully understood how these regulated devices could shape the industry and patient care moving forward, but it is clear that mobile applications, as medical devices, are becoming more prominent and garnering focus from regulatory agencies. Future and more comprehensive analyses may help to better understand the existing gaps and potential areas for growth.

References

Author Contact Information
Lee V1, Kasbekar S1, Roland K1, Toscani M1
1 Rutgers University Ernest Mario School of Pharmacy

Limitations
While our analysis did provide some insights into the kinds of mobile applications available and which the FDA may focus their regulations on, there were some existing regulated medical devices that were reviewed, but did not meet the criteria for an FDA regulated mobile medical application. These applications were not able to test out the applicability of criteria for regulation. Furthermore, many applications that were reviewed may not have been updated since the first released version, thus these conclusions may be outdated. It is possible these outdated applications are no longer intended for use by patients and therefore may not be relevant to include in the analysis.

Method
The top three pharmaceutical companies, by 2018 revenue, Pfizer, Roche, and Sanofi were selected for this descriptive analysis.2 The available applications for these companies were surveyed through the descriptions posted in the Apple App Store and Android Play. Furthermore, many applications available and which the FDA may focus their regulations on, there were some existing regulated medical devices that were reviewed, but did not meet the criteria for an FDA regulated mobile medical application. The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis. The majority of the applications reviewed did not meet the criteria for an FDA regulated mobile medical application. Only two applications of the 23 total were already registered as medical devices through the 510(K) premarket notification. Roche’s Accu-Chek Connect application met the definition of a device and the predetermined functionality criteria of performing patient-specific analysis.