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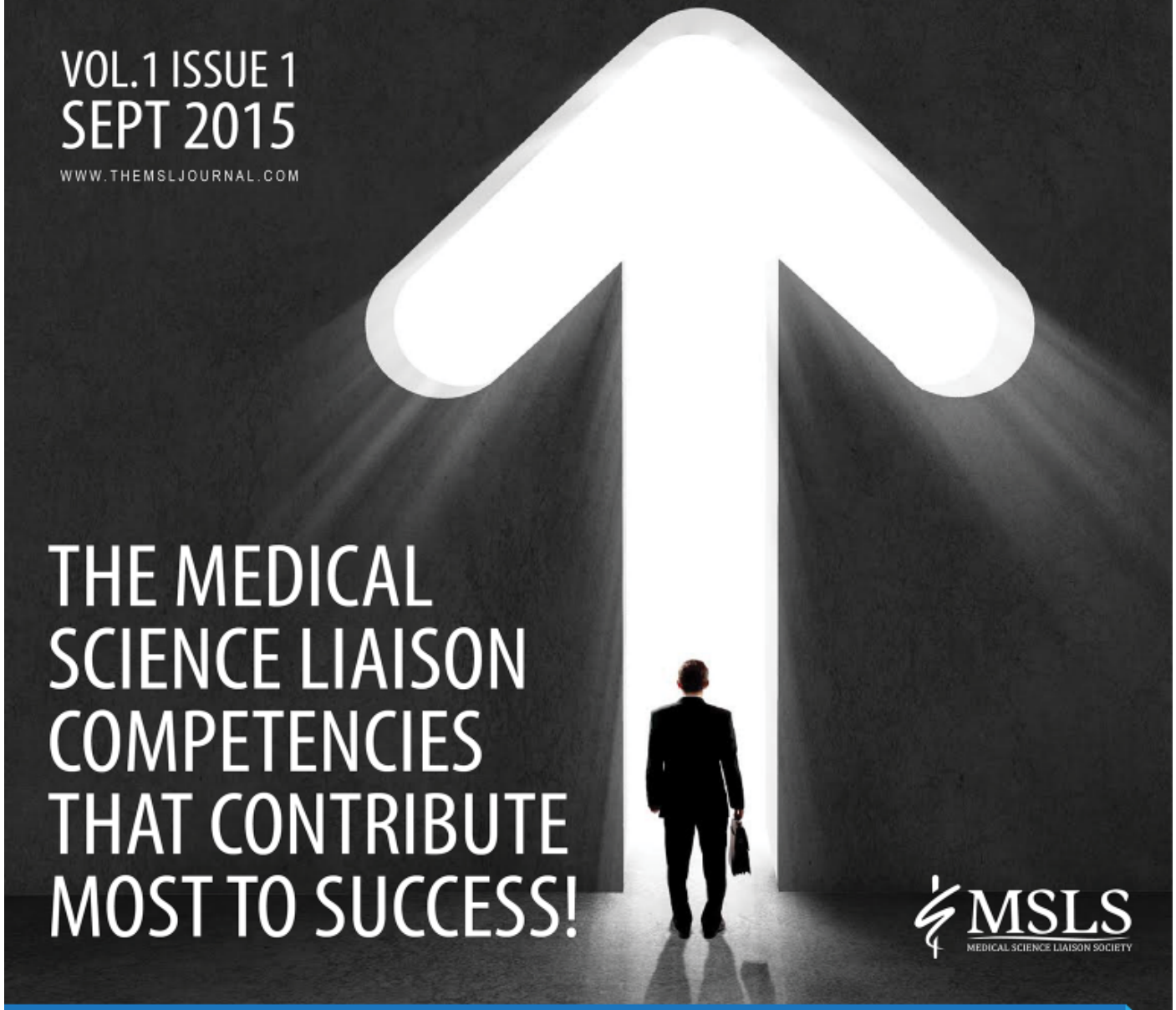

THE MEDICAL SCIENCE LIAISON COMPETENCIES THAT CONTRIBUTE MOST TO SUCCESS!

MSLS
MEDICAL SCIENCE LIAISON SOCIETY

The First Amendment: Physician Education Using Off-Label Indications to Ensure that Patients Receive the most Effective Treatment Part I

The Basis for an MSL Professional Board Certification: An Overview of the Process

Developing the Leaders of the Medical Science Liaison Profession: The Launch of the MSL Society Fellows Program

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Sept 2015

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Welcome from the Chairman of the Board

| Sept 2015

Dear Colleagues,
I would like to extend a personal welcome to the first issue of THE MSL: Journal of the Medical Science Liaison Society. THE MSL: Journal of the Medical Science Liaison Society is the first and only peer-reviewed journal focused on the Medical Science Liaison (MSL) profession. The primary purpose of the journal is to provide a peer-reviewed platform for sharing expertise, insights, research, and knowledge as well as to supply a forum for understanding the issues impacting the MSL profession.

It is fitting to begin our new publication by addressing why the THE MSL: Journal of the Medical Science Liaison Society was created. The Medical Science Liaison role has experienced tremendous growth since it was first established by the Upjohn Company in 1967. Today, all top pharmaceutical companies in the US have an MSL team. More recently, the role has seen explosive growth in other regions as well, particularly across Europe and Asia. How MSLs are utilized has also evolved since it was first conceived by the Upjohn Company. Originally, the MSL function was created to build relationships with key sales customers. Today, MSLs no longer have sales responsibility and increasingly play a crucial role in the success of global companies from the value they bring to Key Opinion Leader (KOL) and other healthcare-provider relationships. THE MSL represents a major milestone in the growth, evolution, and maturity of the Medical Science Liaison profession.

To date, there has never been a journal that specifically caters to the needs of our profession. THE MSL: Journal of the Medical Science Liaison Society aims to fill this need. The journal will act as a focal point for critical research and insights specific to the MSL career as the profession evolves. THE MSL will also act as a venue to raise awareness of the profession itself.

This inaugural issue represents the type of content we plan to publish in future issues. The articles are wide-ranging in topic, global in perspective, and valuable for individual contributors and managing MSLs alike. The authors represent MSL leaders, companies that support and provide services to pharmaceutical companies and MSL teams, and those from academic-fellowship programs focused on Medical Affairs and MSLs. I am confident that both Medical Science Liaison Society members and the broader MSL community will benefit from the content of THE MSL.

I am deeply honored to serve as the Chairman of the Board for the Medical Science Liaison Society. Leading the MSL Society has been the most rewarding and humbling aspect of my career. We have experienced tremendous growth since officially launching as a 501(c)3 nonprofit organization in 2012. In fact, we have doubled in growth each consecutive year! Thanks to our

enthusiastic members, we have participants from 33 countries representing major pharmaceutical, biotechnology, medical device, and other healthcare companies. THE MSL: Journal of the Medical Science Liaison Society will be an important conduit to further expand and connect our global MSL community.

Our new journal represents an important step in our society's journey and goals. The vision of the Medical Science Liaison Society is to be the primary global resource for MSL professionals in the pharmaceutical, biotechnology, medical device, CRO, and other healthcare industries. The journal will help us further this vision by providing valuable, credible information and by serving as the authority in MSL career-related issues.

Since the inception of the Medical Science Liaison Society, it has been one of my goals for the society to have a journal where the global MSL community could access credible information related to our profession. This inaugural issue of THE MSL fulfills this important goal and has been over three years in the making! It took longer than we anticipated, but it is exciting to share the launch of journal and the contents of our first issue. We could not have achieved this without the knowledge and support of Dr. Hudson Garrett, Dr. Alexander Tolmachev, the global advisory committee, and Jeff Kraemer. Dr. Hudson Garrett will serve as the journal's Editor-In-Chief and work closely with authors to publish their work in this exciting new publication. Lastly, we are sincerely indebted to the authors within the pages of this inaugural issue; without your support and contributions, THE MSL would not exist.

The inaugural issue will be presented on Tuesday, September 29, 2015 during our annual U.S. conference hosted by Genzyme in Boston. This is the Medical Science Liaison Society's official journal and is a benefit of membership. We welcome everyone from the global MSL community to contribute to future issues of the journal!

It is a great honor and privilege to share with you the first issue of THE MSL: The Journal of the Medical Science Liaison Society.

Sincerely,

Dr. Samuel Dyer
Chairman of the Board
Medical Science Liaison Society

The Medical Science Liaison Competencies That Contribute Most to Success

| Sept 2015

Introduction

Significant discussion and several recent publications have focused on how the Medical Science Liaison (MSL) role is evolving and on the types of challenges MSLs now face. These realities, unfortunately, aren't going away anytime soon. However, little has been written about what all of these changes mean for effective MSL performance. The MSL role is different today, so what should MSLs do differently to succeed? To provide meaningful answers to this critical question, the Medical Science Liaison Society launched a major, first-of-its-kind, global, quantitative survey in 2015. Our goal with the survey and this report is to provide a clearer understanding of the specific skills and knowledge bases that are most critical to MSL success in today's environment.

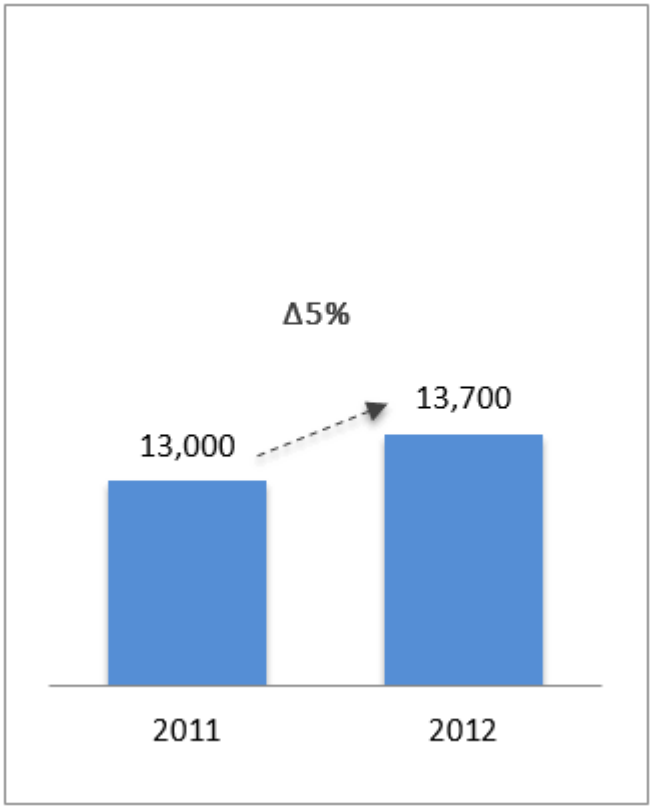
The Challenges

Medical Science Liaisons face a number of challenges that continue to reshape the MSL role, but perhaps the most urgent involves pharmaceutical companies' most critical asset: Thought Leaders or Key Opinion Leaders (KOLs). Seventy-two percent of MSLs and MSL managers expect the number of MSLs to increase globally by 20 percent in just the next one to two years (Figure 1).

Figure 1: Expected Global MSL Growth in the next 1-2 years *(MSLs & MSL Managers)*

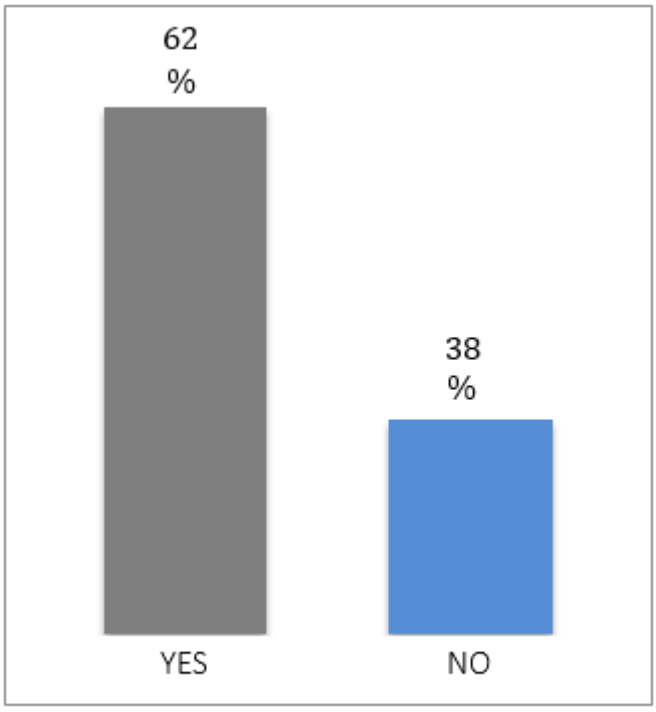
However, demand may be outstripping supply. For example, from 2011 to 2012, the number of oncologists in the US grew by just 5 percent (Figure 2).

Figure 2: Growth of U.S. Oncologists



MSLs are becoming increasingly concerned about access to Thought Leaders or Key Opinion Leaders (KOLs). Data from another recent global survey conducted by the Medical Science Liaison Society underscores this challenge. The results of the survey concluded that 62 percent of MSLs and MSL managers report that KOLs are becoming less accessible (Figure 3).

Figure 3:



n=497

Given the increasing number of MSLs being launched over the next few years, and with the concern that KOLs are becoming less accessible, individual MSLs will need to be more successful during each engagement with a KOL. As a result, competition for a KOL's time will likely increase.

Survey Methodology

To understand what drives MSL performance today and to help MSLs make the right improvements, the MSL Society launched a major quantitative survey. We received responses from 369 MSLs and 199 MSL managers from forty-three countries, with significant representation from every major geographical region in the world and from all main healthcare company types.

The survey focused on 14 competencies (i.e. the skills and knowledge items required for success) for two reasons: (1) competencies are the most basic elements of human performance, and (2) they can be learned/improved. Specifically, we asked MSL managers to rate the MSL competencies that they feel are most important to business success and to indicate how effectively MSLs tend to deliver in light of these competencies. Our objective was to identify any gaps, particularly regarding the competencies that matter most.

Figure 4: MSL Competencies and Methodology

- Analytical Thinking
- Building Partnerships
- Business Acumen
- Communication Clarity
- Emotional Intelligence

- Customer Focus
- Influencing/Persuasion
- Presentation Expertise
- Proactivity
- Regulatory Expertise
- Responsiveness
- Scientific Expertise
- Solutions Orientation
- Value Demonstration

To build this list of competencies, we started with a review of the existing research on the subject of competencies. Next, we sought the opinions of several highly regarded MSL managers from major companies around the world. Finally, with their help, we built the list of competencies listed in Figure 4. The results offer a helpful mix of knowledge, such as Business, Regulatory, and Scientific Expertise, as well as skills like Analytical Thinking, Influencing, and Demonstrating the Value of the MSL role to others.

These specific roles are performed by MSLs in the course of their daily work. To be deemed a "Scientific & Technical Expert," an MSL must use knowledge of science, the regulatory environment, and business to drive specific outcomes for stakeholders. The "Relationship Manager" MSL delivers great service to those with whom he or she works, both internally and externally. Finally, the "Excellent Communicator" MSL uses interpersonal and communication skills to create value for stakeholders and to change the way they think and behave.

Key Findings

First, the average importance scores for each role (noted in each role category) show that the Scientific & Technical Expert is the least important to business success today. That is not to say that scientific and technical expertise are not important. Indeed, the competency receiving the highest importance score is Scientific Expertise, at 91 percent. However, relatively speaking, in the eyes of MSL managers, this role is the least important for driving business outcomes in the current business environment. Put another way, technical skill has become table stakes. These competencies are critical, and MSLs must have them in order to succeed. However, they are not differentiating factors among successful MSLs.

Notice the gaps between importance and effectiveness in the Scientific & Technical role. With the exception of Analytical Thinking and Business Acumen, where there is some room for improvement, MSLs are largely proficient in these competencies. In other words, while MSLs may want to work on their Analytical Thinking and Business Acumen somewhat, these are not the roles where MSLs should spend much of their limited development time.

Now note the Relationship Manager role. For the most part, these results resemble those of the Scientific & Technical Expert. MSLs could be better at Proactivity and with developing solutions to our stakeholders' challenges, but on the whole, MSLs are effective at relationship management. As with the Scientific & Technical Expert, this area is not where MSLs should allocate substantial portions of their limited development time.

Finally, note the Excellent Communicator role. Again, this is the role where MSLs use their interpersonal and communication skills to create value for stakeholders. As indicate by the survey data, this is the role that managers feel is most important in terms of driving business success today. However, note the heights of the grey bars: this is also where MSL managers feel MSLs are the least effective. Being an Excellent Communicator is the most critical role in terms of helping pharmaceutical companies succeed, and yet this is where MSLs have the greatest room for improvement.

What does an Excellent Communicator do exactly?

The Definitions

The below definitions for each of the competencies that relate to the Excellent Communicator role. Here are several important aspects:

- **Communication Clarity:** Excellent Communicators do not simply use language that everyone can understand; they *tailor* their communications for the right audience.
- **Building Partnerships:** Excellent Communicators build creative and diverse networks. And because they are good listeners, they "activate" these networks, capturing rich and valuable information.
- **Value Demonstration:** Excellent Communicators are effective at not only communicating the value they create for others, but also in continually identifying new sources of value for stakeholders.

- **Influencing/Persuasion:** Excellent Communicators understand what motivates others, and they use this knowledge to help stakeholders appreciate their point of view.
- **Emotional Intelligence:** Excellent Communicators are attuned to social and psychological cues. They use this information not only to know what to say, but also to determine *when* and *how* to say it.

In short, Excellent Communicators use their emotional intelligence to sense stakeholder needs. They use their abilities to communicate clearly, to influence, and to persuade as a means of engaging stakeholders' interest. In addition, they use their partnership and value-demonstration skills to add value.

Conclusion and Discussion

With increasing competition for KOLs' time, a new set of competencies is required for modern MSL success. While scientific and technical expertise and relationship management remain core requirements of the MSL role, these competencies have become table stakes, no longer providing unique value for KOLs or other business partners. As the results of this first-of-its-kind study demonstrate, MSLs who wish to outperform their peers and to differentiate themselves need to strive to become Excellent Communicators.

MSL managers rate the Excellent Communicator role as the most important for business success. This is most likely due to three factors:

1. **Demand for Insight.** In the current digital age, KOLs or Thought Leaders are regularly bombarded by vast amounts of information of varying quality. As a result, they want MSLs who can help separate the signal from the noise and provide information that is relevant and valuable. This requires Communication Clarity and the ability to Demonstrate Value.
2. **Demand for (Human) Networks.** Business today is increasingly interconnected, particularly in the global world of healthcare. Therefore, KOLs and business partners value MSLs who create and capitalize on interpersonal networks, both within and across organizations. This requires Emotional Intelligence, Partnership Building, and Influence/Persuasion.
3. **Skill Scarcity.** The skills that make up the Excellent Communicator role are highly nuanced and sophisticated. In addition, they rarely receive the development attention they deserve. This makes the Excellent Communicator skills less common, boosting their worth.

Interestingly, while MSL managers feel the Excellent Communicator role is the most important in terms of driving success, it's also where they see the greatest room for improvement. As a result, MSLs should spend their limited development time enhancing their Excellent Communicator skills.

References:

1. 2014 Global Survey, The Medical Science Liaison Society, 2014.

Tablet Computer Utilization and Satisfaction among Field Medical Personnel: Trends from 2011-2014

| Sept 2015

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Abstract

Background: This study aimed to build upon research from 2011 and 2012 to assess trends in preferences, satisfaction, and functionality of tablet computers in addition to applications (apps) used among Field Medical Personnel. *Methods*: A web-based, anonymous survey was disseminated to United States Field Medical Personnel. Findings were compared to 2011 and 2012 results to assess trends. *Results:* A total of 113 respondents who self-identified as Field Medical Personnel completed the survey. Overall, 93% of respondents reported utilizing a tablet for work, an increase of 4% from 2012 and 48% from 2011. Compared with prior years, tablets are being increasingly utilized for nearly all unique functionalities. The most common apps reported for different functions include Concur for expense reporting (72%) and travel management (52%); WebEx® for tele/video conferencing (60%); iBooks® for presentation of clinical trial information (16%); Microsoft PowerPoint® for presentation of slides (19%); PubMed for performing literature search (22%); and Web Browser, Salesforce®, and Veeva® for documenting key opinion leader interactions (12% each). While Field Medical Personnel are using tablets for expanded functionalities, 50% of respondents would like to retain use of their laptops in the field, 33% prefer to eventually only use tablets, and 17% remain undecided. These preferences were consistent with 2012 data (46%, 32%, and 21%, respectively). *Conclusions:* This study provides evidence that tablets have become more ubiquitous in their usage by Field Medical Personnel since the original 2011 investigations and continued monitoring of technology trends is important to ensure that field medical departments remain current and effective in today's competitive pharmaceutical environment.

Keywords [5-6 words]

iPads®, tablets, MSL, Medical Science Liaisons, Field Medical Affairs, trends

Tablet Computer Utilization and Satisfaction among Field Medical Personnel: Trends from 2011-2014

Introduction

About five years after the launch of the iPad® in 2010, tablet computers (tablets) have become an essential tool utilized within several business sectors.[1] One such sector, the pharmaceutical industry, has increasingly adopted tablets to facilitate medical affairs team personnel activities, especially those of Medical Science Liaisons (MSLs). MSLs practice as field-based scientific experts employed to develop and maintain professional relationships between pharmaceutical companies and healthcare providers (HCPs) through the provision of medical and scientific information regarding the company's products and related therapeutic areas. For MSLs, tablets have proven useful for many functions in their daily practice. To enhance thought leader engagement, MSLs utilize the tablet to readily retrieve information, such as slide presentations and interactive demonstrations. MSLs can also utilize the tablet to assist with their various administrative functions while traveling, including travel management, expense reporting, and documenting thought leader interactions.

With this advancement in technology, research on the adoption and utility of tablet was assessed in a study conducted by Monera et al. in 2011, one year after the launch of the iPad®. At the time of the study, 45% of MSLs who completed the survey reported using a tablet in the field.[2] One year later, in a study conducted by Haile-Meskale et al., the utilization of tablets among MSLs was again explored and demonstrated dramatic expansion of tablet usage, with a near doubling to 89%.[3] Given this widespread increase in a one-year timeframe, it is of special importance to continue research in this area to further define trends related to the growing adoption of this technology. Therefore, a third survey was conducted to capture preferences, satisfaction, and functionality of tablets among field medical personnel in the present day and to further compare these findings to previous research results.

Methods

From July 7, 2014 to October 1, 2014, a web-based, anonymous survey consisting of up to 32 questions was disseminated to US field medical personnel representative of various pharmaceutical and biopharmaceutical companies (see Supplementary Data Table S1 for survey questions). The study protocol was approved by the Rutgers University Institutional Review Board and informed consent was obtained from each survey respondent. Field medical personnel, in this study, were comprised of MSLs, MSL supervisors, and health outcomes liaisons (field experts in health economics and outcomes who liaise between payer customers and pharmaceutical companies), hereafter referred to collectively as MSLs. Survey questions were designed to assess preferences, satisfaction, and functionality of tablets in addition to tablet applications (apps). MSLs were identified through a variety of mediums, including the Rutgers Pharmaceutical Industry Fellowship alumni database; individual field medical directors who disseminated the survey to their respective MSL teams; members of the MSL Society; and through the MSL LinkedIn groups MSL World and The Medical Affairs Company. Personal identifiable factors (e.g., name, company, and contact information) remained anonymous and respondents were able to discontinue the survey at any time. MSLs that discontinued the survey prior to completion had their partial responses included in the analysis. For this reason n value variances between questions are due to these partial responses. Results of this survey (representing 2014 data) were compared to findings from research conducted in 2011 and 2012 to define trends in the evolving integration of tablets by MSLs in the present day.

Results

One hundred and fifty-one (151) MSLs within the pharmaceutical industry from across the United States (US) responded to this survey. One hundred and thirteen (113) MSLs continued on past the first question. This was an increased response value compared to previous years, as 88 MSLs responded to the 2012 survey and 77 MSLs responded to the 2011 survey.

Educational background and tenure as an MSL are outlined in Figure 1 and Figure 2, respectively. The respondents worked for companies of various sizes, as presented in Table 1. The MSLs who responded to the survey were fairly evenly distributed across the US; with about 33% covering the Northeast, 35% covering the Southeast, 26% covering the Southwest, 31% covering the Midwest, and 33% covering the West Coast (see Supplementary Data Figure S1 for territory delineations).

Figure 1: Educational Background

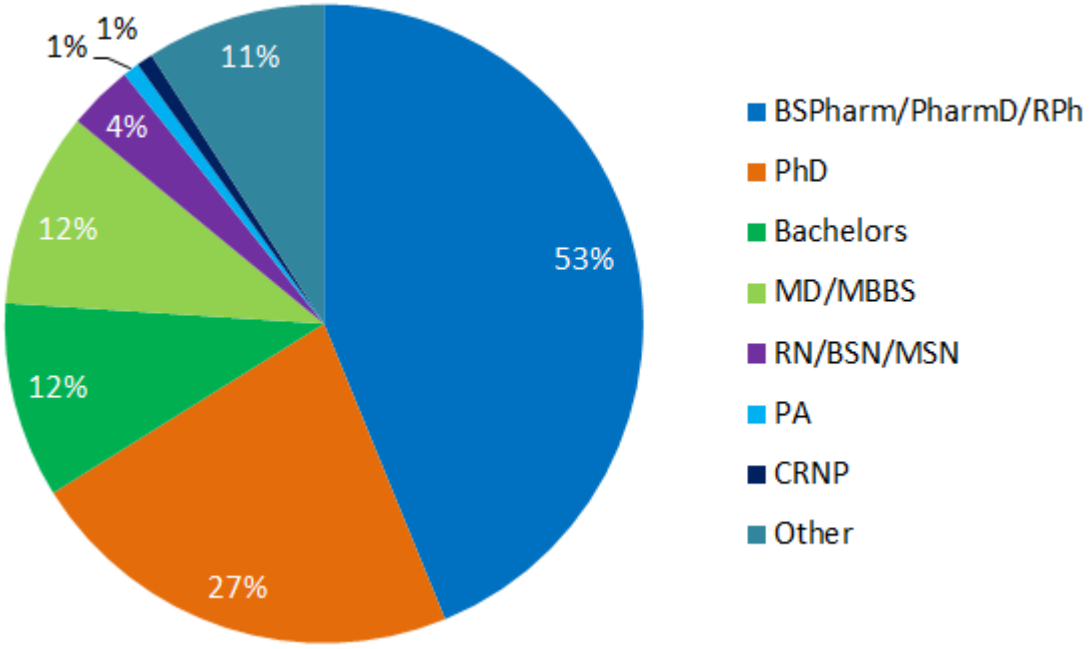
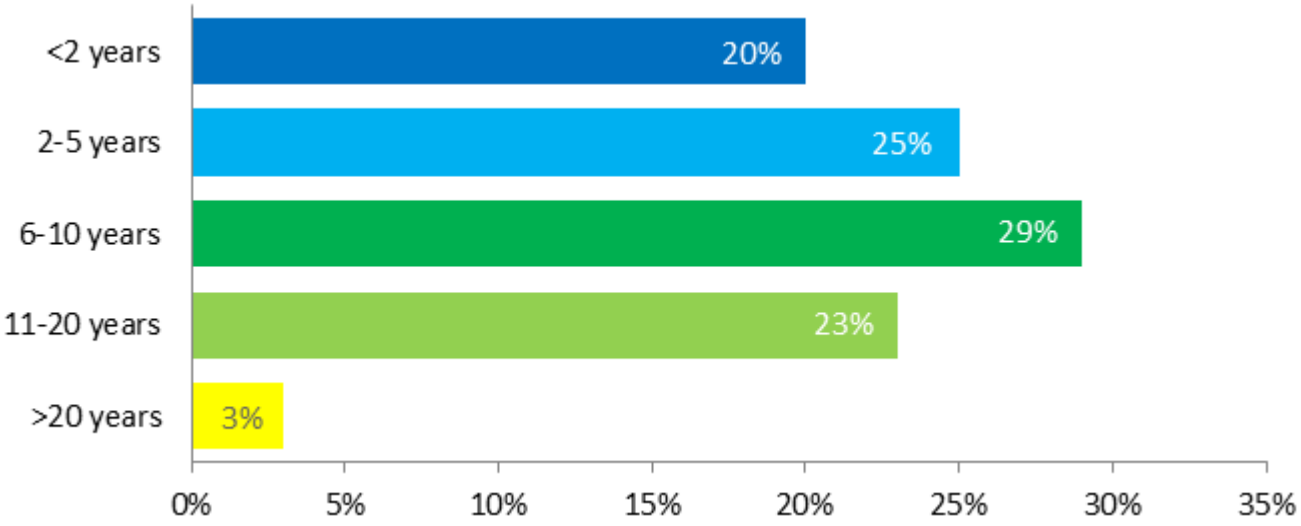


Figure 2: Years of Field Experience

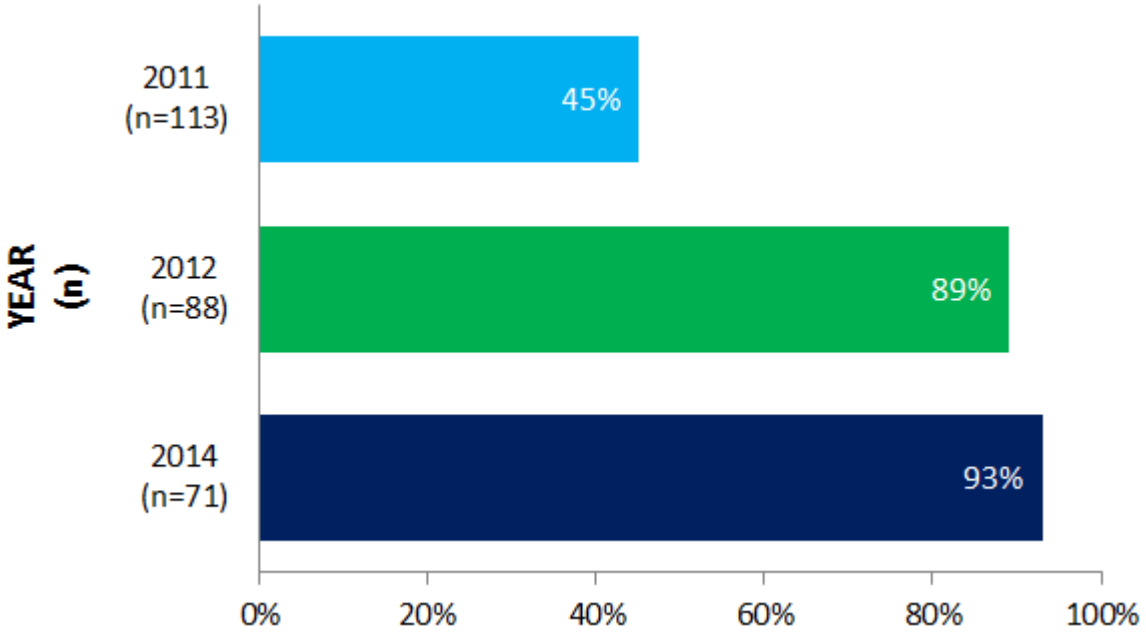


# OF EMPLOYEES	% OF RESPONDENTS
≥ 10,000	28%
5,000-9,999	19%
1,000-4,999	25%
< 1,000	27%

Table 1. Size of Company

Overall, 105 out of 113 (93%) of the MSLs reported that the Field Medical Department at their company uses tablets. Figure 3 shows tablet use throughout the previous years. Eleven percent (11%) reported using a tablet for less than 6 months, 6% for 6-12 months, 28% for 1-2 years and 49% for over 2 years. Of the MSLs who use a tablet, all reported using an iPad®.

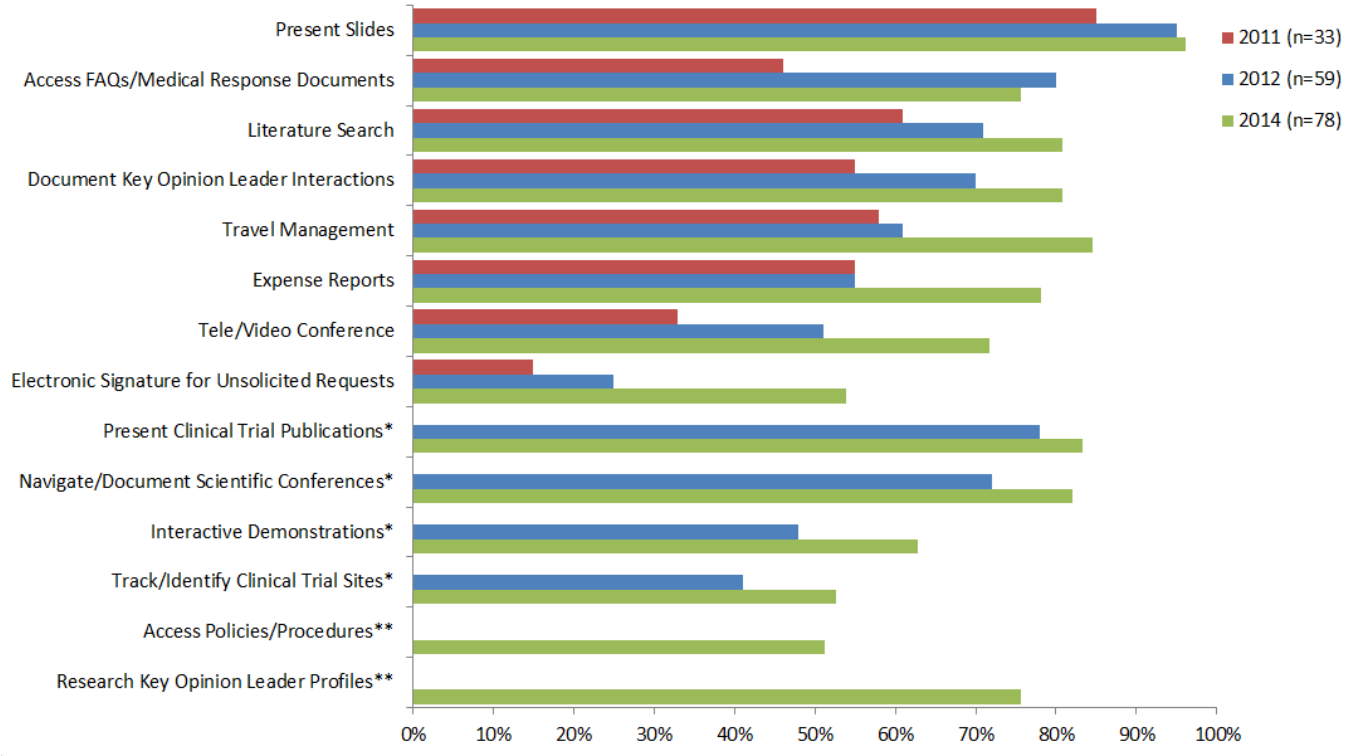
Figure 3: Use a Tablet for Work



Device Utilization

Among the respondents using tablets, the business and scientific functions of the tablet were analyzed and compared to prior years (Figure 4). The top six uses for tablets by the MSLs surveyed in 2014 are as follows: presenting slides (96%), travel management (85%), presenting clinical trial results through publications (83%), navigating and documenting a scientific conference (82%), conducting literature searches (81%), and documenting key opinion leader (KOL) interactions (81%).

Figure 4: MSL Tablet Uses



Functionality Satisfaction

MSLs rated their satisfaction with the use of a tablet for various business and scientific functionalities using a 5-point Likert scale, with 1 representing very dissatisfied and 5 representing very satisfied (Figure 5). The functions with the highest percentage of MSLs reporting very satisfied or satisfied are as follows: presenting clinical trial results through publications (77%), accessing FAQs and medical response documents (75%), travel management (73%), presenting slides (72%), and expense reporting (72%). The satisfaction levels reported in 2014 were largely consistent with those reported in previous years (Figure 6)

Figure 5: Satisfaction with Tablet Functionalities

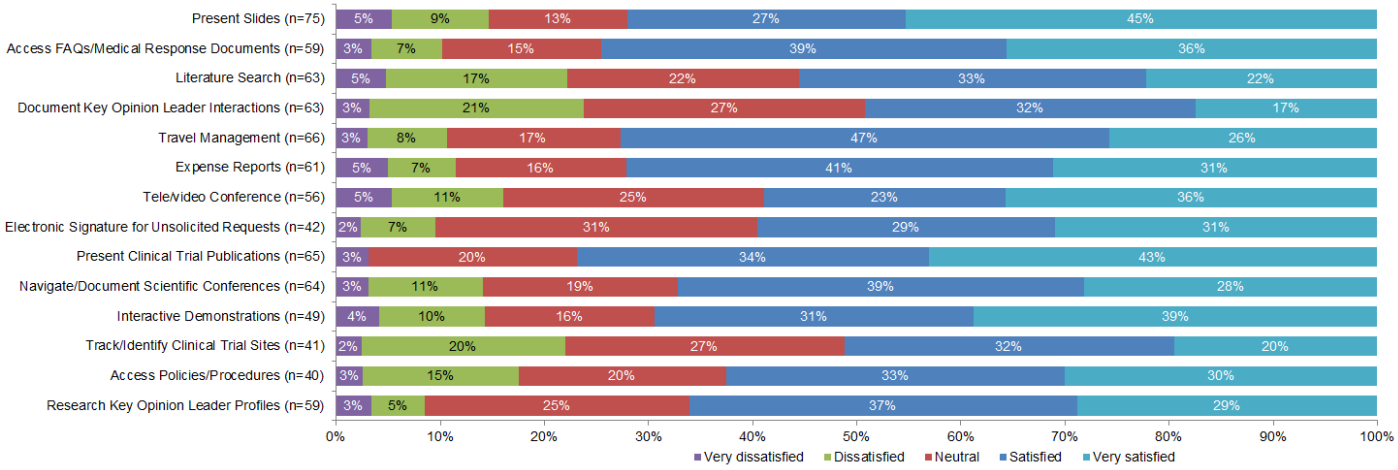
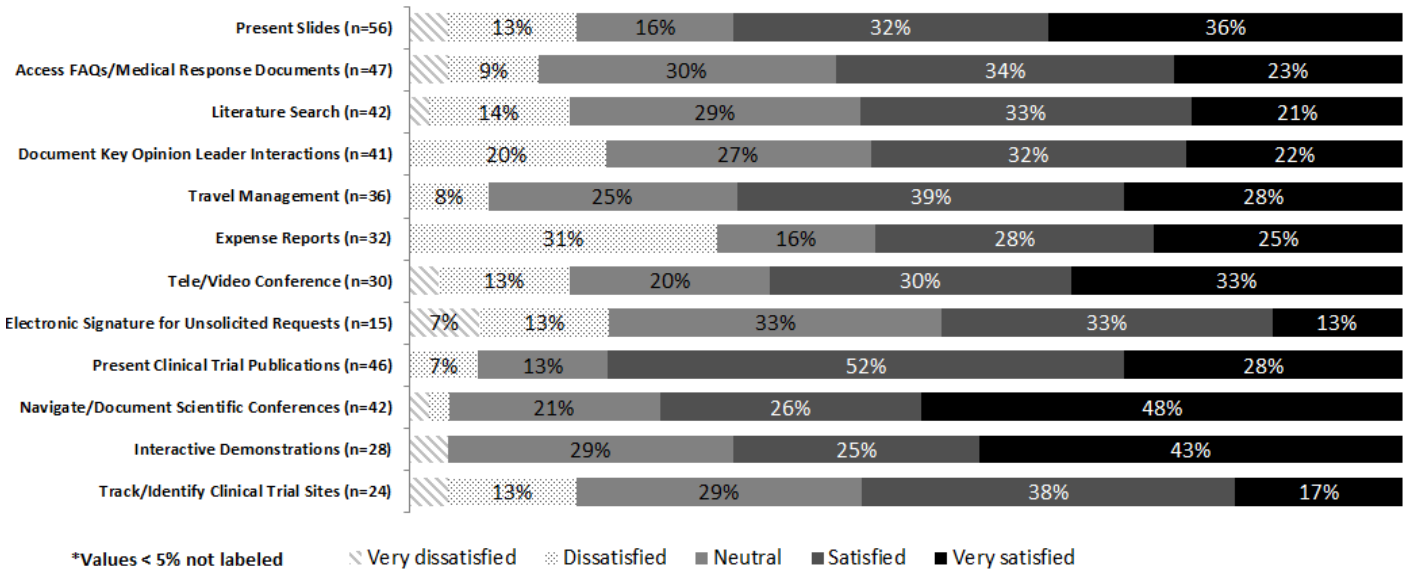


Figure 6: Satisfaction with Tablet Functionalities in 2012



Device Preference

Device preference was analyzed for each function among MSLs who use tablets. The tablet was preferred over the laptop for the following five functionalities: navigating/documenting scientific conferences, presenting clinical trial results through publications, presenting slides, interactive demonstrations, and capturing an electronic signature for unsolicited requests (Figure 7). Despite the noted preference among responders, there were a large number of MSLs reported interactive demonstrations and capture of an electronic signature for unsolicited requests functionalities were not applicable to their jobs (32% and 37%, respectively). The results regarding device preference are consistent with preferences reported in previous years (Figure 8).

Figure 7: Device Preference

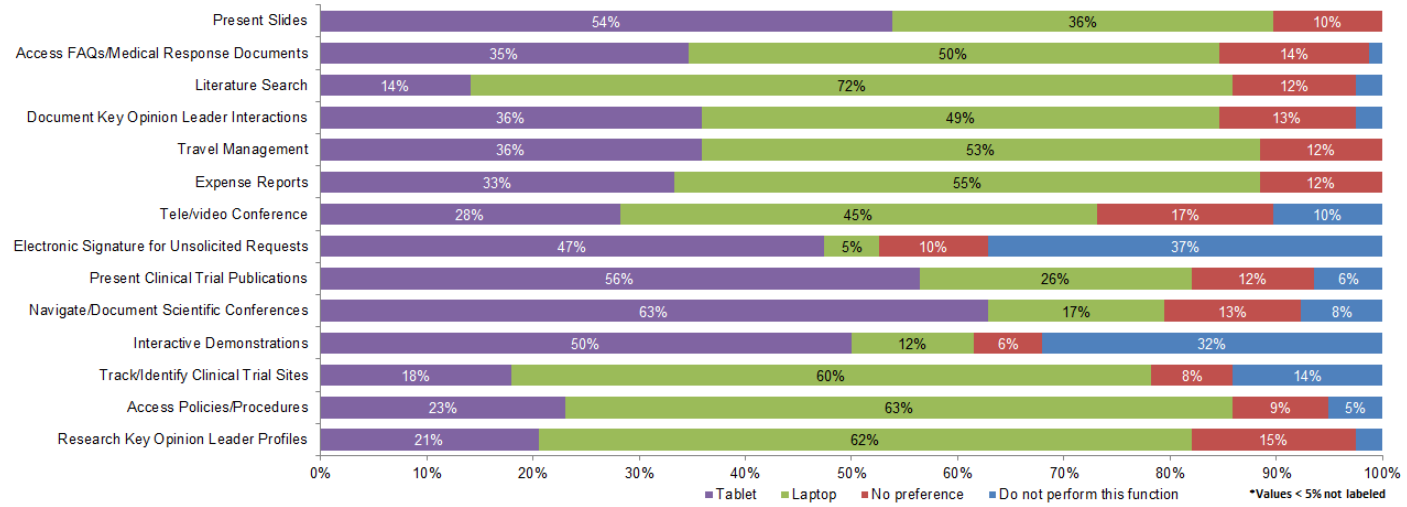
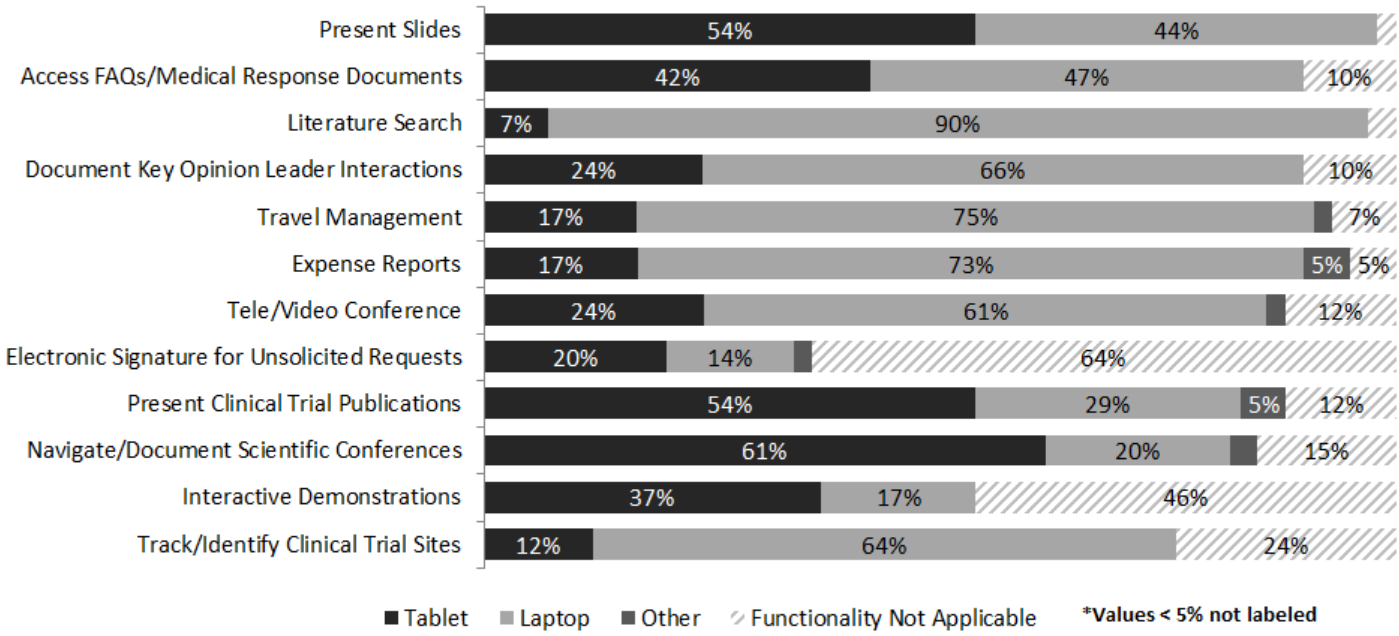


Figure 8: Device Preference in 2012



Device preference varied based on whether or not the device was being used in the field. When in the field, 45% of survey respondents (n=35) use their tablet more than their laptop, while only 23% (n=18) use their laptop more than their tablet, 19% (n=15) use both technologies equally, and 12% (n=9) do not use their laptop at all. Conversely, when not in the field, all respondents (n=78) reported using a laptop to some extent, and 67% (n=52) are using a laptop more than a tablet. Half of respondents (n=39) do not want to switch someday to a tablet-only approach, while 33% (n=26) reported they would switch, and 17% (n=13) are undecided.

Limitations of Using a Tablet

Key limitations of using a tablet reported by MSLs include connection availability to internet and/or intranet, lack of compatibility with Microsoft®-based applications (Word, Excel, PowerPoint, etc.), lack of keyboard, optional external keyboard being too small, small screen size, difficulty multitasking, and limited available apps.

App Preference

Survey respondents reported which apps they used for each functionality (Table 2). This was an open-ended question in the survey, allowing respondents to report multiple apps for the same function. The MSLs reported 21 unique apps for presenting slides, with Microsoft PowerPoint® being mentioned most frequently (14 instances). This is a change from 2012, where Keynote® was the most frequently reported app for presenting slides (Table 3). Company-developed apps were most frequently reported for several of the functions, including capturing electronic signatures for unsolicited requests and interactive demonstrations. Company-developed apps were most reported for navigating and documenting scientific conferences, which is a change from 2012, where Evernote® was most reported (see Supplementary Data Table S2 for full listing of app-related responses).

Table 2. App Preference in 2014

	# Apps Reported	# Unique Apps Reported	Apps Most Frequently Reported (# Times Reported)
Present Slides	75	21	PowerPoint (14)
Access FAQs/Medical Response Documents	31	19	Company app (10)
Literature Search	49	16	PubMed (11)
Document Key Opinion Leader Interactions	50	21	Browser (6), Salesforce (6), Veeva (6)
Travel Management	52	18	Concur (27)
Expense Reports	53	10	Concur (38)
Tele/Video Conference	45	11	WebEx (27)
Electronic Signature for Unsolicited Requests	22	11	Company app (7)
Present Clinical Trial Publications	38	20	iBooks (6)
Navigate/Document Scientific Conferences	56	26	Congress app (10)
Interactive Demonstrations	24	11	Company app (9)
Track/Identify Clinical Trial Sites	19	11	Browser (6)
Access Policies/Procedures	41	14	Company app (10)
Research Key Opinion Leader Profiles	47	12	Browser (21)

Table 3. App Preference in 2012

	# Apps Reported	# Unique Apps Reported	Apps Most Frequently Reported (# Times Reported)
Present Slides	46	17	Keynote (10)
Access FAQs/Medical Response Documents	15	11	No Majority
Literature Search	20	5	Web Browser (5)
Document Key Opinion Leader Interactions	20	11	iRep (5)
Travel Management	18	7	Concur (12)
Expense Reports	23	3	Concur (21)
Tele/Video Conference	20	6	WebEx (13)
Electronic Signature for Unsolicited Requests	5	4	Company-Developed (2)
Present Clinical Trial Publications	20	9	Good Reader (6), iBook (6)
Navigate/Document Scientific Conferences	17	10	Evernote (5)
Interactive Demonstrations	4	3	Company-Developed (2)
Track/Identify Clinical Trial Sites	5	5	No Majority

When asked about the biggest challenge with specific apps, respondents reported issues with apps hanging, crashing, or timing out. MSLs also mentioned that Dropbox®, GoodReader®, and Box® may not display PowerPoint slides correctly. SlideShark® seems to remedy this issue but respondents mentioned that it has a cumbersome uploading process, and it does not allow for editing capabilities. The Microsoft® Office Suite of apps has been recommended by some respondents to display and edit Microsoft® documents (including PowerPoint slides), though respondents reported a long loading time. While the Concur® app was the most popular choice for travel and expenses, respondents reported a sluggish experience. Finally, there were some respondents who reported incompatibility with the iOS calendar and MS Outlook®, which caused some meetings to be altered or even deleted. Despite these challenges, it must be acknowledged that they are based on reports from specific versions of the apps at the time of survey, which may not be representative of future and updated versions.

Formatting Content

Content can be specifically created for use on a tablet or converted from its original format to a format suitable for a tablet. For example, since all MSLs reported currently using an iPad®, some companies may need to implement a solution for converting Microsoft PowerPoint® slides to a format that is more compatible and displays better on the Apple operating system. In some cases, companies opt to recreate slides and content as a stand-alone app. In 2014, 72% of MSLs reported that their company develops content by converting it to a format that is suitable for tablets, while 14% stated that their company develops content specifically designed for the tablet.

Tablet Training

The type of training provided to the MSLs on how to use the tablets varied. No training was provided for 26% (n=27) of the total

respondents. Of the other 74% (n=77), several MSLs reported receiving either a live or virtual training session, often with the Information Technology (IT) group, while others reported receiving both live and online training sessions. For some, the online virtual training was one single session, whereas for others, it consisted of an ongoing program with multiple modules. Some MSLs also reported receiving written instructions, either to supplement the live and virtual training sessions or, occasionally, as a substitute to a live or virtual training session. One MSL reported that beyond receiving the initial training, their team has two "tech champs" who answer questions on an ongoing basis and that their MSL trainer is available to assist with challenging problems and act as a liaison with IT. The content of the training sessions also differed. Some MSLs reported receiving training on just how to use the apps, often specifically the company-developed apps, while others received basic general device training, including a review of its functionality and battery saving tips. Overall, 64% (n=67) reported that the tablet training they received was adequate, and 10% (n=10) reported that it was inadequate.

For those that reported that they received no training or that their training was inadequate, when asked what type of training they would have wanted, they provided conflicting responses. Some stated that no training was needed, while others were split between preferring additional basic training on iPad® capabilities, more hands-on training, more app-specific training, or a more thorough demonstration of both all capabilities and how to use each app.

Unsolicited Requests

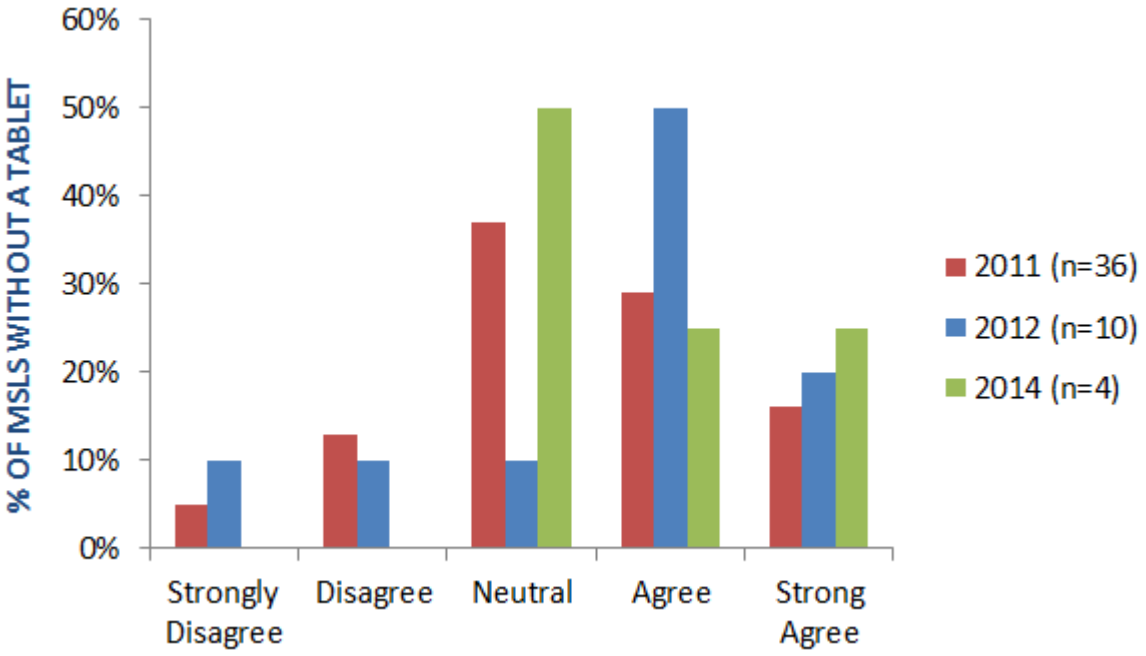
The survey respondents (N=78) were fairly split on how they captured unsolicited requests using their tablet, with 44% reporting they do not use their tablets at all to document or respond to unsolicited requests, while 42% reported using their tablet to capture information requested from the KOL. About one-third (35%) reported using a stylus pen or finger to capture KOL signatures, and another third (36%) sent the request directly from their tablet to the medical information department for fulfillment.

The survey respondents (N=78) were also somewhat split on whether their company required them to capture signatures for unsolicited request. About half (53%) are required to capture signatures: 17% need to do so for both on- and off label requests, while 36% reported needing to capture signatures just for off-label requests. Forty-seven percent (47%) reported that they are not required to capture signatures at all, which is lower than 2012, where 61% of the MSLs reported not needing to capture signatures.

MSLs Who Do Not Have Tablets

Out of the 113 MSLs surveyed, only 7 reported that the Field Medical Department at their company does not use tablets. When asked why their company had not adopted tablets, most reported cost saving. Only four out of seven respondents completed the remaining questions. Half of those four respondents agreed or strongly agreed that not having a tablet is a disadvantage, while the other half were neutral. The survey respondents explained they believed it was a disadvantage because a tablet provides easy access to data, allows one to be more interactive, and would streamline many actions. The lack of any disagreement differs from results from previous surveys; in 2012, 20% disagreed or strongly disagreed, and in 2011, 18% disagreed or strongly disagreed (Figure 9). When asked which scientific and business functions they would use their tablet for if they had one, all of the functions were selected by at least one respondent, with all agreeing they would use it for documenting KOL interactions, travel management, and expense reports.

Figure 9: Not Having a Tablet is a Disadvantage



Discussion

In 2014, 93% of respondents reported that their field medical department uses tablets, which compares similarly to 89% in 2012 while demonstrating a drastic increase from the 45% in 2011. This steep initial increase from 2011 to 2012 indicated the rapid uptake of tablets that ultimately later plateaued in 2014 as tablets reached essential complete market penetration. Almost half of all respondent companies have been utilizing tablets for over 2 years, and all respondents reported specifically using the iPad®. In previous years, however, one respondent reported using a Google™ Nexus as their tablet of choice.

For training, the majority of respondents stated that the tablet training they received was adequate, but 10% of respondents did not consider their training adequate, and 26% did not receive any training. There were several reports stating that they received specific training on company-developed apps, and it seemed that the amount and type of training depended on how much companies utilize certain or company-specific apps. While most respondents mentioned adequate training, there does not seem to be standard level of training between companies. There also appears to be a disparity regarding the amount of training desired, since respondents may have varying degrees of familiarity with tablets and technology. Due to these discrepancies, it seems practical that companies provide training to individual MSLs on a case-by-case basis, tailored to their knowledge level.

Between 2012 and 2014, there was a > 5% increase in satisfaction with the use of tablets to access FAQs/medical response documents, for travel management and expense reporting, as well as for capturing electronic signatures for unsolicited requests. There was a corresponding > 5% decrease in satisfaction with the use of tablets to document KOL interactions and navigate conferences. This may be due to companies developing their own apps to navigate conferences, burdening MSLs with multiple systems (i.e., a company-developed conference app and an official conference app). Satisfaction with all the remaining tablet functionalities remained fairly consistent from 2012 to 2014.

When the MSLs are in the field, the majority of them report using their tablets more than their laptop; whereas when they are not in the field, the majority of respondents reported using their laptop more than their tablets. The preference for tablets in the field may be due to the nature of functions typical to the field (e.g., presenting slides or clinical trial publications), where a lightweight and portable technology platform with a simple interface is valued. This preference also relates to the satisfaction reported for those tablet functionalities typically conducted in the field, as tablet satisfaction was relatively high. The preference for laptops when conducting more administrative and/or research-based functions (e.g., documenting KOL interactions, literature searches, or tracking/identifying clinical trial sites) seems to correlates to the lower level of satisfaction with those functions on the tablet (Figure X). Some administrative tasks, such as travel management and expense reports, were reported to have a high

level of satisfaction on the iPad®, perhaps due to the ease of use of the most commonly referenced app for this function, Concur®. However, respondents still prefer using the laptop for these tasks.

Overall, 50% of respondents do not want to switch to only using a tablet, while one-third do. This is consistent with the results from the 2012 survey and seems to define where field medical personnel are finding iPads® useful and not useful. In the 2011 survey, MSLs reported battery life, access to VPN, full capability with most websites, and ease of printing as limitations to using the tablet. The 2014 survey, however, did not report these limitations, as the market has responded to address some of these challenges. Over time, there have been increases in the battery life, VPN and mobile-friendly websites have become widely available, and there is improved compatibility with programs like Microsoft Office® (Office 365). Also, third-party Bluetooth keyboards are addressing the consistently reported limitation of a lack of keyboard. Nonetheless, until most of the challenges with using the tablet are addressed through advances in technology, or the level of comfort with these challenges adapts, the laptop will remain an essential device for MSLs.

Developers continually create apps to meet the demands of the tablet user, and MSLs have numerous options when selecting an app for a particular functionality. Some companies, however, place restrictions on the type of apps approved for download and/or reimbursement, which may limit the options available for MSLs. Of the apps reported by respondents, there are some functions with a well-established consensus app, some with several options available, and others that need the customization of a company-developed app.

Functionalities such as travel, expenses, navigating conferences, documenting interactions, and tele/video conferencing all have a majority consensus app. Concur® is the decisive app for both travel and expenses, possibly due to convenience of the app and/or the predominance of Concur® usage within corporations. At scientific conferences, most respondents report using conference-developed apps for both navigation and scheduling. An increasing number of conferences are now creating their own specific apps for attendees to download, so scientific communication departments may be able to reduce efforts in creating conference media for their attending employees. In documenting KOL interactions, most teams are using Veeva® (AKA iRep® or Salesforce.com®) or a company-specific app, although the customizable Veeva® seems to be the consensus tool for field medical affairs teams. Finally, the majority share of tele/video conferencing services belong to WebEx.

Several functionalities, such as displaying slide decks and publications, have several options for MSLs to choose, as each app provides certain strengths and weaknesses. To display slide decks, the PowerPoint app from the *Microsoft Suite*® is the most popular, while other options include *Keynote*®, *SlideShark*®, and *GoodReader*®. To share publications with KOLs, many MSLs lean toward the PDF apps *iBooks*®, *PDF Expert*®, *Adobe*®, and *GoodReader*® to display these documents. The decision to use one of these apps over another seems to be based on MSL preference. Since the PowerPoint is Microsoft-developed, it ensures compatibility between PowerPoint decks, something with which many of the other apps seem to struggle. However, this PowerPoint app provides read-only access unless the user has a subscription to edit the documents.

In some cases, such as interactive demonstrations and accessing FAQ and Medical Letters, apps available through the tablet may not suffice, so companies have responded by creating their own company-specific apps. While most MSLs do not use tablets for interactive demonstrations, those that do are using company-specific apps, indicating that home-grown or vendor-created apps are required to customize the content. To access FAQ and Medical Letters, most respondents are using company-specific apps or secure websites, probably because the documents contain proprietary information. The majority of respondents do not use tablets to access policies and procedures, but if they do, it is through a company app. Perhaps this could also be due to the sensitive nature of the documents.

While apps in general can provide an easy and intuitive user interface for most functions, sometimes a simple browser will suffice. This seems to be the case for literature searches, identifying clinical trial sites, and researching KOL profiles, as the majority of MSLs prefer to use the Apple iOS Safari or alternative web browsers for these tasks.

Although there appear to be a number of app options available for various functionalities, survey respondents still listed a variety of issues they face with the apps they are using. There seems to remain an opportunity for app developers, including IT departments within pharmaceutical/biotechnology companies, to improve capabilities specific to MSL scientific and business functions.

Limitations

There were several limitations inherent in the study design. The first is the inability to guarantee equal representation of MSLs across companies due to the anonymity of the survey. This concern may be compounded by the dissemination provided by field directors to their respective teams, and over-representation of companies with large Rutgers Pharmaceutical Industry Fellowship alumni representation. Second is that some respondents did not complete the survey, with unequal responses for each question. Third, there are differences in individual survey respondents in each yearly survey, potentially making differences in preferences drawn across survey years not due to changes in attitude regarding tablets, but instead implicit in the uniqueness of each survey respondent. Fourth, due to the limited sample size, definite conclusions cannot be drawn from the data, nor can they be generalized to all pharmaceutical and biotechnology companies. Finally, the survey may be biased toward technology users as respondents were reached via technological means (e-mail, MSL websites, etc.).

Conclusion

This study provides evidence that tablets have achieved almost complete adoption by MSLs since the original 2011 analyses completed by Monera, et al. In addition to increased utilization across individuals, the functionality and variety of uses is increasing. Given these findings, continued monitoring of technology trends, specifically unique apps used, among MSLs is warranted. Awareness of the rapid and ever-changing landscape is important in ensuring that field medical departments remain current and effective in today’s competitive pharmaceutical environment.

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The First Amendment: Physician education using off-label indications to ensure that patients receive the most effective treatment.

| Sept 2015

Abstract: In today's medical environment, a two-fold element of risk affects a medical device company. This risk is comprised of the risk of improper treatment through the agent's lack of scientific disease-state knowledge, as well as the medical-device company's fiduciary duty to ensure patient safety through facilitating proper education for the physician. The Food, Drug, and Cosmetic Act serves as the body of law that regulates the marketing of medical-device products in the United States, which restricts off-label marketing and advertising. To date, proponents have argued that off-label utilization is a First Amendment right necessary to ensure that patients receive the most effective treatment.

What is off-label use?

Off-Labeling involves anything a company or an employee produces or presents in a promotional message that is not consistent with the approved product designation, regardless of whether it is truthful, accurate, and reflective of good medical practice (1). The use of any drug or treatment that incorporates a medical device is considered to be off-label if it is false or misleading, or if it does not have an indication for specific uses (1). Pharmaceutical and medical-device companies are prohibited from promoting the off-label use of their products, such as advertising a certain device for use with children when it is only indicated for adults (1).

Abundant examples exist for the reality of this predicament. Sudden cardiac death is a leading cause of death among adults over the age of 40 in the United States and other countries, but its treatment is considered an off-label use by some medical-device and pharmaceutical companies (2). Despite occurring at an average of 60 years of age, it continues to claim the lives of people during their most productive years. Similarly, Temperature Management is a new treatment option available in most hospital systems that may not only mitigate brain damage resulting from anoxic encephalopathy after Sudden Cardiac Arrest (SCA) but may also control fever in several disease states (3). Utilization in this capacity, however, is regarded as off-label by Temperature Management companies in the United States. This may constitute a compliance issue on behalf of the medical-device company, one with a potentially vast array of consequences insofar as the promotion of off-label education to physicians

and other healthcare practitioners is concerned.

When SCA occurs, blood stops flowing to the brain, the heart, and the rest of the body, causing the person to collapse. In fact, SCA renders the victim clinically dead, a state during which time, in the absence of immediate assistance, the body and brain will be subject to serious and perhaps irreversible harm (4). Each year, 424,000 people in the U.S. (more than 1,000 per day) experience EMS-assessed, out-of-hospital, non-traumatic SCA, and nine out of ten of these victims die. This is roughly equivalent to the combined number of people who die from Alzheimer's disease, assault with firearms, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor-vehicle accidents, prostate cancer, and suicides. In fact, the incidence of sudden cardiac death is nearly ten times higher than the incidence of death from breast cancer (4-7).

The U.S. Federal Drug Administration restricts off-label promotion—which includes print media, brochures, websites, lectures, and face-to-face communication—by employees of a medical-=device or pharmaceutical company when there is no indication for use (8). The statutory framework under the FDA regulates sales and marketing by a series of statutory provisions, as interpreted by the FDA through the Food, Drug, and Cosmetic Act of 1938 (FDCA) (9). Physicians may only prescribe off-label medications and devices if the physicians are not employed by the medical or pharmaceutical companies in question. Even if the physician is an agent of the company, any verbalization of accurate and truthful information regarding off-label use provides grounds for the prosecution and conviction of a federal crime (8). In this review, the term "off-label" will be used to convey specific indication as well as false or misleading promotion.

Physicians who practice in a hospital have a choice regarding the prescription of off-label uses for medical devices; this choice can bestow certain important advantages (8). First, it allows greater innovation in clinical practice, particularly when other approved treatments have failed. An example of such an occurrence might take place after a stroke patient has been administered Tylenol or a similar medication for the control of fever. If this treatment should prove ineffective, the off-label employment of a fever-control device could provide the necessary relief. This form of action is imperative, given the deleterious effects that inadequately controlled states of fever can exert upon the neurological recovery of patients (3). Although this example is hypothetical, the off-label use of certain treatments is nevertheless invaluable because it offers patients and physicians access to potentially lifesaving options that might be dismissed otherwise. This could enable physicians to adopt new practices based on emerging evidence, rendering off-label usage—unlike other treatment options—devoid of stasis due to its adaptability. Moreover, treatment options of this variety are the only ones available for "orphan" conditions (10).

At the same time, however, off-label use can produce negative consequences, most of which result from the lack of systematic evaluation. This is the case when evidence from one clinical situation is applied to another presumptuously. The expectation is, of course, that since safety and efficacy have been fully evaluated in the case of the former, the same results can be expected for the latter, regardless of the disease state involved. Clearly, these notions are erroneous. When newer, more expensive options are used in an off-label manner, it increases healthcare costs by de-incentivizing manufacturers to perform due diligence in designing and participating in clinical studies, encouraging them instead to seek approval for secondary indications for which clinical trials are less complicated and less expensive (10). Currently, the general legality and value of off-label uses is integral for medical practice. Any ambiguity related to the matter was removed by the decision of the Supreme Court in Buckman Co. v. Plaintiffs Legal Committee, which states that "[O]ff-label use is generally accepted" in medicine, and under the law, "[p]hysicians may prescribe drugs and devices for off-label uses" (531 U.S. 341, 351 & n.5, 2001). However, manufacturers are limited as to what they may give to physicians as educational resources (8).

Physicians may benefit from proper education provided by the company that directly manufactures the device. Since it is the fiduciary duty of the company to ensure patient safety, proper education should be offered to the physician (10). Other educational resources of particular benefit are medical and science journals, newsletters, seminars, websites, and peer influence on behalf of colleagues. It can be difficult, if not altogether improbable, for a single physician to keep up with the hundreds of publications written each year (12). The direct link for up-to-date information would be the source itself, namely the company that manufactures a specific device (13). But how is this to be accomplished when FDA policy bans all speech relating to the subject, regardless of whether it is false or misleading in nature? (8). It has been stated that the greatest threat to the medical and pharmaceutical industry in the domestic United States may be its own policy environment, a dilemma undoubtedly brought about by the restriction of truthful dialogue with physicians about their product (14).

The authority of the FDA, however, does not extend to the practice of medicine, and the regulations it imposes do not prohibit physicians from prescribing approved devices and drugs to treat conditions for which they believe the products are indicated (15). Here the issue of negligence becomes a relevant topic, as the probability of inadvertent patient harm increases when physicians lack the proper knowledge and training for the application of off-label medications and devices. Without understanding either the physiological changes that occur with individual disease states or the potential ramifications of the treatments prescribed for them, the physician places the patient in an unnecessarily precarious position that can lead to claims of negligence in the event that the patient is harmed (16). Such harm arises because of the direct link that exists between off-

label indication and the absence of education from the manufacturer.

The next section explains several organizational goals that ensure compliance with FDA guidelines for the distribution of off-label information and material by manufacturers. The use of field representatives is a fundamental component of the medical-device or pharmaceutical sales models. Yet interactions between the field representatives and healthcare practitioners (HCPs) often pose compliance risks for manufacturers, such as the risk of off-label promotion and the provision of perceived kickbacks. Monitoring, both retrospectively and in real-time, identifies the risks inherent in these interactions and serves as part of a risk-mitigation strategy (17, 18).

Scientific Dialogue vs. Marketing:

There are a few exceptions to the proverbial rule by which the FDA permits the distribution of off-label information by manufacturers. The first of these, known as the "bona-fide scientific dialogue" (hereafter BFSD), deals with promotional activity accomplished by marketing. As its title implies, the BFSD permits manufacturers to discuss information regarding the off-label use of its products through a scientific dialogue or an exchange of information that is not conducted in a promotional setting. The second exception occurs as a response to unsolicited requests for information about unapproved uses. Manufacturers in these cases may distribute information concerning off-label use "in response to unsolicited requests for scientific information from health care professionals," so long as the response is characterized by balanced, scientific material that is non-promotional (19). The initial inquiry, moreover, must not have been prompted through a sales or marketing effort made to encourage, target, or otherwise solicit a physician with questions or requests regarding off-label use (19).

Standard of Care and Legal Theories: Potential Third-Party Consequences

Underlying the off-label argument is a fiduciary responsibility and an obligation for individuals who are trusted to act in the best interest of their clients. Theoretically speaking, the responsible party should be transparent in its dealings and personally accountable for its results. Physicians often fail to think of themselves in this role (that is, as constituents of the responsible party). Nevertheless, the generation of income through unnecessary medical services is substantial evidence of an improper purpose. (see Scott, 107 N.M. at 122, 753 P.2d at 901 (20)). From the manufacturer's standpoint, soliciting the off-label use of a product to increase profits is a violation of false-claims policy (19).

As soon as the physician-patient relationship comes into existence, the physician can be held liable for an intentional refusal of care or treatment under the theory of Abandonment. (Abandonment is an intentional act; negligent lack of care or treatment is medical malpractice.) When a treatment relationship exists, the physician must provide all necessary treatment to a patient unless the relationship is terminated by the patient or by the physician himself, provided that the physician gives the patient sufficient notice to seek another source of care. Most doctors and hospitals routinely ensure that alternative sources of treatment are made available for patients whose care is being discontinued (21). As previously mentioned, the arguments for and against off-label use constitute a diverse dialectic with no general consensus. This is even more problematic since off-label use is capable of bringing innovation to clinical practice, especially when other approved treatments have failed (10).

One potential issue of abandonment in a patient's care is the denial of prescribed medication. In numerous cases in most conceivable contexts, this may constitute the standard of care (Layzer v. Leavitt, 770 F. Supp.2d 579 (S.D.N.Y. 2011)). Layzer involved Medicare coverage of an off-label use in a recurrent context, namely that of a rare disease for which no on-label treatment existed because the small market size did not justify the costs associated with undertaking the studies the FDA requires to support a labeled indication. Medicare denied coverage in this case because the particular off-label use fell outside of the government's definition; it was neither on-label, nor apparent in any of the specific compendia of compensable off-label uses. The court held, as a matter of law, that the government's position (including regulation) concerning what was "medically accepted" was invalid (770 F. Supp. At 587).

Off-label uses offer significant benefits to patients by allowing greater access to potentially valuable treatment options. Physicians also stand to be impacted positively. Through the adoption of new practices based on emerging evidence, physicians can avail themselves of a greater wealth of conceivable treatment resources, an accomplishment which can only enhance the prosperity of ailing patients (10). Proponents of off-label use argue that medical-device companies are in the best position to ensure patients receive the most effective treatment by educating the physician in the mitigation of potential risk (23). At the same time, off-label use has potentially negative consequences. Uses of this nature have not been evaluated systematically, and evidence provided for one clinical situation may not apply to others. As a result, expectations regarding safety and efficacy are undercut (10). Despite these concerns, off-label prescribing is a necessary practice of medicine (14).

Conclusion

The conflict between the First Amendment and public health is certainly here to stay, but it has been minimized effectively by the Second Circuit Court's stance on free speech. The current imposition of a near-complete and criminal ban on off-label speech is, considering its potential to save a considerable number of lives, most definitely indicative of the government's overreaching and overly broad interpretation of policy. The application of off-label uses has met a new frontier with the use of the Central Hudson four-prong test, which has narrowed the government's interest. This will perhaps lend a more transparent view to what is acceptable when speaking with physicians regarding off-label use. In today's medical environment, a two-fold element of risk affects medical-device companies: (A) the risk of improper treatment through the agent's lack of scientific disease-state knowledge, and (B) the medical device company's fiduciary duty to ensure patient safety by providing proper education for the physician. This seems curtailed by the body of law promulgated by the Second Circuit's view of off-label use and the narrowing of the range of substantial government interest.

In a world where increasingly sophisticated technological advances in healthcare and medicine such as Targeted Temperature Management are allowing people to live longer, more active, and more fulfilling lives—even after life-threatening events and illnesses that would have formerly been regarded as irretrievably fatal—certain limitations impede the course towards what could be the apogee of medical and legal progress. This is made all the more disconcerting by the restriction of the most basic of our Constitutional freedoms, free speech, with regards to the off-label utilization of pharmaceutical drugs and medical devices.

While the world of healthcare continues to evolve at an unprecedented rate into a state of nearly unbelievable and even futuristic proportions, the state of the law that governs its applications appears to be lacking to an extent bordering on the static and antediluvian. If society as a whole, instead of singular aspects like medicine and healthcare, is to reach a suitable state in the near future, one elevated to an extent directly proportional to the progress made in other key areas since its inception, greater attention must be given not only to the more effective enforcement of current laws, but also to the status of laws themselves. Indeed, it seems nearly paradoxical that legal aspects governing the practice of potentially life-saving medications and devices in an off-label manner are allowed to exist where lives are at stake. Nevertheless, the debate between free speech and off-label promotion lingers. In this context, it seems a reasonable goal that this divergent argument should reach a suitable conclusion, one that upholds the basic tenets of the law while emphasizing to the utmost degree the importance that medical progress plays in the sustainment of human life. If the necessity of human life should prove incompatible with the legal aspects governing it, any further discourse or dialectic on this subject shall be rendered unnecessary.

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26. Advanced **Cardiac** Life Support, Ken Grauer and Daniel L. Cavallaro, Mosby Lifeline, St. Louis, MO.
27. Johns, supra note 109, at 981.
28. Robert Steinbrook, Gag Clauses in Clinical-Trial Agreements, 352 New Eng. J. Med. 2160, 2160 (2005) ("Sponsors with a financial interest in the outcome of clinical research can suppress negative results.").
29. Stafford, supra note 13; see also Donna T. Chen et al., U.S. Physician Knowledge of the FDA-Approved Indications and Evidence Base for Commonly Prescribed Drugs: Results of a National Survey, 18 Pharmacoepidemiology & Drug Safety 1094 (2009).
30. Wilhoit v. Boehringer Ingelheim Pharmaceuticals, Inc., 2009 WL 702007, at *3-4 (D. Minn. March 13, 2009)
31. Natasha Singer, Medical Papers by Ghostwriters Pushed Therapy, N.Y. Times, Aug. 4, 2009, at A1 (regarding recent allegations related to this practice).
32. John Ford, a Parke-Davis marketing manager, reportedly encouraged the company's medical liaisons to promote Neurontin for off-label uses for which there was no apparent scientific or medical basis:

I want you out there every day selling Neurontin…. We can't wait for them to ask, we need to get out there and tell them up front…. That's where we need to be, holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything.

Disclosure of Information by Relator David P. Franklin Pursuant to 31 U.S.C. § 3730 b(2), 11 (1996), available at http://dida.library.ucsf.edu/pdf/rab00a10.

33. See Press Release, Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care

Liability Relating to Off-Label Promotion (May 13, 2004), http://www.justice.gov/opa/pr/2004/May/04_civ_ 322.htm. In a more recent case, Eli Lilly was accused of illegally promoting its drug Zyprexa (olanzapine). Zyprexa, the first in a new class of so-called atypical antipsychotics, was approved by the FDA in 1996 for the treatment of schizophrenia and in 2005 for the treatment of bipolar disorder. Following FDA approval of the second indication, the record suggests that Eli Lilly shifted its marketing strategy such that its sales representatives would indicate to general practitioners that Zyprexa was appropriate for elderly patients suffering from depression or dementia. In announcing its settlement, the government emphasized the primacy of the FDA's role, suggesting that any information provided by companies outside of the FDA-approved message would necessarily "undermine the integrity of the doctor-patient relationship and place innocent people in harm's way." Eli Lilly settled these allegations in early 2009 for $1.415 billion. Press Release, Dep't of Justice, Eli Lilly and Company Agrees To Pay $1.415 Billion To Resolve Allegations of Off-label Promotion of Zyprexa(Jan.15,2009),http://ww.justice.gov/civil/ocl/cases/Cases/Eli_Lilly/Lilly%20Press%CC20Release%CC20Final%C¨civ-038.pdf.

34. Rockoff, Allergan Suit Seeks to Lift Botox Curbs, Wall St. J., Oct. 2, 2009, at B4; Natasha Singer, Botox Maker's Suit Cites Free Speech, N.Y. Times, Oct. 3, 2009, at B3.

35. United States v. Caronia, No. 09-5006-cr, 2012 WL 5992141, at *1 (2d Cir. Dec. 3, 2012).

36.*Id.* at *4. Xyrem is a "powerful central nervous system depressant," which at the time of Caronia's alleged misconduct had been approved by the U.S. Food and Drug Administration ("FDA") solely to treat narcolepsy patients for cataplexy (a condition associated with weak or paralyzed muscles). *Id.* at *3. Soon thereafter, Xyrem was approved by the FDA to treat narcolepsy parties with excessive daytime sleepiness. *Id.*

37.*Id.* at *4.

38.*Id.* at **4-5. The government never asserted that Caronia's statements about Xyrem were false or misleading. Id. at *13 n.11. Rather, the government's claims were based entirely on the theory that Caronia had promoted or participated in promoting Xyrem for unapproved uses and/or patients populations. Id. at * 9.

39.*Id.* at **5, 7. Prior to trial, Caronia moved to dismiss the charges against him on the ground that the FDCA provisions at issue impermissibly and unconstitutionally restricted his First Amendment right to free speech. Id. at *6. The district court denied that motion, and the case proceeded to trial. Id. Orphan and the physician it hired as a promotional speaker were also charged under the misbranding provisions of the FDCA, and both pled guilty. *Id.*

40.*Id.* at *8.

41. United States v. Caputo, 288 F. Supp. 2d 912, 921 (N.D. Ill. 2003); WLF I, 13 F. Supp. 2d at 69
42. Central Hudson Gas & Electric Corp. v. Public Service Commission
43. Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 239 (3d Cir. 2012).
44. Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989).
45. Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 589 F.3d 881, 884 (7th Cir. 2009)
46. Richardson v. Miller, 44 S.W.3d 1, 12 (Tenn. App.2000), appeal denied (Tenn. March 12, 2001).
47. Riley v. Cordis Corp., 625 F. Supp.2d 769, 784 (D. Minn. 2009).
48. U.S. Food and Drug Administration, Guidance for Institutional Review Boards and Clinical Investigators: "Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices. 1998 Update. http://www.fda.gov/oc/ohrt/irbs/offlabel.html
49. U.S. Food and Drug Administration, Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared medical Devices. January 2009. http://www.fda.gov/oc/op/goodreprint.html

Overview of the MSL Society Fellowship Program

| Sept 2015

Introduction

One of the main objectives for the existence of the Medical Science Liaison (MSL) Society is to foster the professional growth of the Medical Science Liaison Society. In support of this goal, the MSL Society recently created a professional board certification for the MSL profession that validates core cognitive competencies for the MSL role. In addition, MSL professionals with extensive professional experience, academic credentials, and documented contributions to the profession deserve a pathway for recognition for their achievements that is external to their employer. Consequently, the MSL Society has designed a Fellows program to allow qualified and approved candidates to achieve the Society's highest level of professional recognition, namely the achievement of Fellows Status and the designation of Fellow in the Medical Science Liaison Society (FMSL). This designation would serve as the pinnacle accomplishment for a career in the MSL arena, recognizing the elite leaders and professionals who have met the rigorous criteria for designation as a Fellow.

Requirements for MSL Fellowship

The Academy of the Medical Science Liaison Society will formally award the designation of Fellow to professional MSLs who meet the criteria for admission into the Academy. The following are the required items for acceptance into the Academy of the Medical Science Liaison Society:

- Professional experience as a Medical Science Liaison for a minimum of eight (8) years
- A minimum of a Master's Degree from a regionally accredited educational institution
- Two recommendations from current MSL Fellows
- Submission of a completed application
- Payment of the application fee for Fellows consideration
- Paid, active membership of the Medical Science Liaison Society
- Demonstrated leadership in the MSL profession as evidenced by documented contributions to the MSL Society, the journal, and other professional advocacy issues relates to the profession
- Current certification as a MSL-BC from the Medical Science Liaison Society

Candidates approved by the Fellows Committee will be awarded the designation of FMSL for five years, after which time renewal will be required. All accepted Fellows will be inducted formally at the annual conference held in the US in the Fall.

Fellowship Process

The process for an MSL to apply for fellowship status begins with the self-assessment, which must be completed before the candidate can apply. This self-assessment allows each professional to evaluate their current professional situation with regards to the MSL profession (i.e. years of experience, academic education, continuing education, title with employer, etc.) and to ensure he or she meets the criteria for the designation as a fellow. If the candidate does not meet the specified criteria, then he or she can create an action plan to develop the content areas with opportunities for improvement. The application may be resubmitted after meeting certain criteria detailed above. Candidates who meet the criteria to apply may submit a formal application along with all required supporting documentation. Upon receipt, the application will be reviewed by a committee of three existing MSL professionals who have already achieved Fellows status within the Academy of the Medical Science Liaison Society. The committee will vet all applications, and a formal vote will be taken regarding the acceptance or denial of each application within 90 days of receipt of the initial application. All applicants will be provided with a response in writing of the committee's decision. Candidates that are approved for Fellow's status will be provided with the appropriate details on the proper use of the designation and the credential FMSL.

Maintenance of Fellows Designation

Professional designation of as a Fellow in the Academy of the Medical Science Liaison Society requires an ongoing commitment to the Society and to the profession itself. As a result, professionals wishing to maintain their designation must meet the following criteria,:

- Continuous, active membership in the MSL Society
- Maintenance of MSL Certification through the MSL Society
- Leadership contributions in the form of webinars, journal submissions, participation in the Advisory Board, and related activities in support of the MSL Society
- Payment to the MSL Society for renewal of the Fellows Designation every five (5) years

Discussion

Professional Certification is an important means of demonstrating professional and cognitive competency. The new availability of Fellows status within the Medical Science Liaison Society will enable tenured MSLs and MSL managers and executives to achieve the highest level of professional recognition from the Society and to demonstrate their commitment to the profession. The MSL Fellows program will be launched officially in the fourth quarter of 2015, along with the new professional board certification. For more information, please visit www.themsls.org.