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THE FIRST AMENDMENT:
Physician edication using off-label indications to ensure that patients receive the most effective treatment. Part II

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MEDICAL SCIENCE LIAISON SOCIETY

An Overview of the 2016 National Patient Safety Goals

Global Survey of Medical Science Liaison Job Satisfaction

TeamSTEPPS: An Innovative Approach to Addressing Communication Gaps Across the Healthcare Delivery System

January 2016

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

By Jennifer Williams, PhD, JD, MBA, RN, MS | January 2016

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Part Two

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

Abstract: In today's medical environment there is a two-fold element of risk that affects a medical device company. It is comprised on the one hand by the risk of improper treatment through the agent's lack of scientific disease state knowledge, and on the other by the medical device company's fiduciary duty to ensure patient safety, including the facilitation of proper education to the physician. The body of law that regulates the marketing of medical device products in the United States is the Drug and Cosmetic Act, which places a restriction on 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.

A treatment for cardiac arrest using Targeted Temperature Management (TTM) or Therapeutic Hypothermia (TH) Off-Label but it is a Standard of Care

Pharmaceutical and Medical device companies are prohibited from promoting the off-label use of their products, as is the case when a certain device is advertised for use with children when it is only indicated for adults (1). Sudden cardiac death is a leading cause of death among adults over the age of forty in the United States and other countries, but its treatment is considered an off-label use by some medical device and pharmaceutical companies (2).

For adult patients with out-of-hospital cardiac arrest (OHCA) from a shockable rhythm, Therapeutic Hypothermia (TH) is a standard of care (24, 25). This is a level one recommendation from the American Heart Association, which indicates that one or more randomized clinical trials wherein the lower limit of CI for treatment effect exceeded the minimal clinically important benefit. On the basis of the published evidence to date, the ILCOR ALS Task Force has made the following recommendations:

> Unconscious adult patients with spontaneous circulation after out-of-hospital
>
> cardiac arrest should be cooled to 32°C to 34°C for 12 to 24 hours when the
>
> initial rhythm was VF. Such cooling may also be beneficial for other
>
> rhythms or in-hospital cardiac arrest.

An excellent source of standards for cardiac care is contained within the ACLS manual, a two-volume set of comprehensive guidelines for cardiopulmonary resuscitation (CPR) and the diagnosis and treatment of cardiac events (26). The first volume, subtitled "Certification Preparation," deals with the essentials of running a code, including key algorithms for CPR, essential drugs, treatment modalities and basic arrhythmia interpretation, the essentials of airway and intravenous (IV) access, including management of the airway, ventilation and IV access, and the "perils and pitfalls" of providing basic life support, including administration of drugs, defibrillation, and arrhythmia interpretation (26).

Negligence

A duty of care is a legal obligation imposed upon an individual that requires adherence to a standard of reasonable care while performing acts likely to harm others. Duty of care is the first element that must be established to proceed with an action in negligence. In an action alleging malpractice, the plaintiff has the burden of proving in light of the state-of-the-art technology existing at the time of the alleged malpractice that:

(a) The defendant, if a general practitioner, failed to provide the plaintiff with the recognized standard of acceptable professional practice or care in the community in which the defendant practices or in a similar community, and that as a proximate result of the defendant failing to provide that standard, the plaintiff suffered an injury.

(b) The defendant, if a specialist, failed to provide the recognized standard of practice or care within that specialty as reasonably applied in light of the facilities available in the community or other facilities reasonably available under the circumstances, and as a proximate result of the defendant failing to provide that standard, the plaintiff suffered an injury. [M.C.L. § 600.2912a(1); MSA 27A.2912(1)(1).] (15).

Physicians are experts in the field of medicine, and, concomitant with any such dutiful occupational, there exists a responsibility to put the welfare of one's patients before all else. Off-label uses, however, limit the extent to which medical information, on behalf of the manufacturer, can be disseminated to these physicians. The most obvious negative consequence capable of arising

from such restricted dissemination is the increased potential for negligent practices. The proponents of off-label use further argue that physicians are “best able to evaluate the information and insure that patients receive appropriate treatment,” a declaration supported by the American “learned intermediary” tort doctrine (27). The off-label proponents contend that the FDA prohibits dissemination of critical information that is medically valid; it is harmful not only to the physician and the patient but to the public interest as well (28). Manufacturers have an important duty to act in a manner that is medically and ethically appropriate, by communicating truthful, non-misleading scientific and medical information that supports sound

medical practice. And it is for this reason that they should not be subjected to civil or criminal liability (29).

Off-label use can not only exist in a manner that does not violate the standard of care, but, in many cases, it can actually constitute the standard of care as such. Plaintiffs have tried to incorporate tactics that make it seem as if the utilization of an off-label pharmaceutical or device constitutes medical malpractice per se. This type of claim, though, has not been successful. In fact, such claims have failed miserably: courts have not agreed with plaintiff’s claims that an off-label use may in itself violate the duty of care because such use is both legal and generally accepted as the FDA does not intend to regulate the practice of medicine. Wilhoit v. Boehringer Ingelheim Pharmaceuticals, Inc., 2009 WL 702007, at *3-4 (D. Minn. March 13, 2009).

Cases

Here are just two of several cases wherein accusation of off-label promotion to generate sales is a primary factor. The first concerns Parke-Davis, the unit of Warner Lambert which produces Neurotin (gabapentin), an FDA approved treatment for seizures associated with epilepsy. Parke-Davis employed technical medical writers, acting as ghostwriters, to compose the Neurontin drug profile. Physicians were then remunerated in exchange for placing their names on the publications as authors. This act of legerdemain was perpetrated in order to promote the drug for a multitude of off-label uses, including the treatment of pain, anxiety, and depression, none of which were approved for use in the series of treatments cited (31). Parke-Davis also employed “medical liaisons” to solicit physicians to prescribe Neurotin for other similar off-label indications. One of the participating physicians brought a qui tam action against the company alleging violations of false claims. Evidence that was subsequently confiscated in the case included various sales presentations which not only directed sales representatives to promote unapproved and off-label uses, but even went so far as to equate off-label use to “money” in a contemptible display of corporate cupidity (32). This allegation was settled for $430 million dollars (33).

Another pharmaceutical that was alleged for off-label use is Allergan. The makers, however, brought an action against the FDA and the Department of Justice (DOJ) in federal district court in Washington (34). This lawsuit was brought to determine if a number of FDA regulations are unconstitutional. The company asked for preliminary and permanent injunctions that would enjoin the government from taking civil or criminal action against Allergan on truthful and non-misleading speech. This was a unique case as it detoured from the path taken by similar cases in which the First Amendment had been used as a defense by companies accused of proliferating false and misleading information (34). To date, similarly intrusive governmental investigations have led to the pay-out of billions of dollars in criminal and civil penalties (14).

In December of 2013, the United States Court of Appeals for the Second Circuit reached the conclusion that the regulation and near total ban of off-label use is overly-broad and vacated the conviction of Alfred Caronia, who had been tried and convicted of an unlawful conspiracy to introduce a misbranded drug into interstate commerce in violation of the U.S. Food, Drug and Cosmetic Act (the “FDCA”) (35). Caronia was hired by Orphan Medical, Inc. as a special sales consultant and began to participate in the company’s speakers program. He enlisted practicing physicians to promote the drug Xyrem to other healthcare physicians (35). A government cooperator recorded conversations between Caronia and another physician hired as a promotional speaker, wherein the uses of off-label indications for the use of Xyrem in an unapproved patient population were referenced (36). Federal investigators found that Caronia was recommending Xyrem to physicians for patients with fibromyalgia, restless legs syndrome, and even chronic fatigue. Under the Federal Food Drug and Cosmetic Act, drug makers are prohibited from marketing drugs for unapproved uses. The government did not assert that the speech was either false or misleading, basing their claim, rather, on the promotion of off-label use (37). Caronia was charged and convicted of participating in an unlawful conspiracy that introduced a drug into interstate commerce within the meaning of the FDCA (38). On appeal to the second circuit court, Caronia argued that his right to free speech under the First Amendment was violated as his words were truthful and did not misrepresent the safety or efficacy of the drug, and, therefore, the government could not prohibit him from truthfully promoting the drug (35). In a 2-1 decision, the Second Circuit held that Caronia’s right to free speech under the First Amendment was indeed violated (35,39,40). This decision could have a far-reaching impact that positively effects a change in not only how free speech in this country is legally construed, but in how medical device companies market their products (31).

As defined by preceding case history, First Amendment protection does not provide a defense for false, fraudulent, or even unintentionally misleading speech. Moreover, the FDA has a substantial interest to protect the public from the unsafe or otherwise ineffective use of medical devices and pharmaceuticals by way of regulating the manufacturers that promote off-label

promotion, see United States v. Caputo, 288 F. Supp. 2d 912, 921 (N.D. Ill. 2003); WLF I, 13 F. Supp. 2d at 69 (41). Thus, the question to be answered is: "is there a less-burdensome alternative that the government could implement in order to regulate the manufacturers of devices and pharmaceuticals?" If the answer is "yes," then the current ban is overly-broad and yet too restrictive for the accomplishment of the government's interests. This is evidenced by the ineluctable failure of the proscriptive test for commercial speech established by the Supreme Court in Central Hudson Gas & Electric Corp. v. Public Service Commission (42).

When the Second Circuit addressed the restrictions on Caronia's speech under the four-part test established by the Supreme Court in Central Hudson Test, the Court determined that the first two prongs of Central Hudson were easily satisfied (42). The first prong dealt with whether or not the speech in question promoted off-label use of approved drugs and constituted a lawful activity that warranted First Amendment protection. The second prong focused on the possibility of the government having a substantial interest in drug safety and the restriction of protected speech. The third and forth prongs previously mentioned, as determined by the Second Circuit Court, could not be satisfied. The third prong concerned the requirement that the regulations at issue directly advance government interest. The Second Circuit stated that an off-label drug use itself is not prohibited, as it does not follow that the promotion of off-label use by a particular class of speakers would further the government's goals in preserving the FDA's drug approval process. Furthermore, reducing patient exposure to unsafe and ineffective drugs (35). Finally, the fourth prong of the Central Hudson test determined if the regulations could be more narrowly tailored to further said government interest. The Second Circuit determined that to impose this complete and criminal ban on off-label use would be more restrictive than is necessary to achieve the goal of furthering the government's interest (35). Therefore, as a matter of law, the Second Circuit overturned and vacated Caronia's conviction.

Off-label devices and uses frequently have therapeutic uses other than the FDA-approved indication. In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 239 (3d Cir. 2012). The fact that the FDA has not approved labeling of a drug for a use does not necessarily establish it is medically and scientific appropriate." Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989). "The decision to prescribe such 'off-label usage' . . . is regarded as a professional judgment for the healthcare provider to make." Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC, 589 F.3d 881, 884 (7th Cir. 2009) (applying Illinois law). "[T]he lack of FDA approval for a drug or device for a particular use does not imply that using the drug or device for that use is either disapproved or improper." Richardson v. Miller, 44 S.W.3d 1, 12 (Tenn. App.2000), appeal denied (Tenn. March 12, 2001). "[O]ff-label usage is not illegal or even disfavored under federal law. Rather, it is an accepted and indeed valuable part of the practice of medicine." Riley v. Cordis Corp., 625 F. Supp.2d 769, 784 (D. Minn. 2009).

The American Medical Association supports the need for physicians to have access to accurate and unbiased information about unlabeled uses of drugs and devices while simultaneously ensuring that manufacturer-sponsored promotions remain under FDA regulation. AMA policy states that the association "supports the dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians, if the independent information is provided in its entirety, is not edited or altered by the manufacturer, and is clearly distinguished from manufacturer-sponsored materials" (12).

CONCLUSION

The conflict between the First Amendment and public health is certainly here to stay, but it has been effectively minimized 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 ability to potentially save a considerable number of lives, most definitely indicative of the government's over-reaching and overly broad interpretation. 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 of what is acceptable when speaking with physicians regarding off-label use. In today's medical environment there is still a two-fold element of risk that affects a medical device company: the risk of improper treatment by way of the agent's lack of scientific disease state knowledge, and the medical device company's fiduciary duty to ensure patient safety by including proper education is facilitated to the physician. This seems curtailed by the body of law that was promulgated by the Second Circuit's view on off-label use and the narrowing of the range of substantial government interest.

In a world where increasingly sophisticated technological advances in the field of health care and medicine such as Targeted Temperature Management are allowing people to live longer, more active, and significantly more fulfilling lives, even after life-threatening events and illnesses that would have formerly been regarded as irretrievably fatal, there remains the lamentable fact that certain limitations are impeding the course towards what could very well be the apogee of medical and legal progress. This is made all the more disconcerting by the fact that the most basic of our supposedly guaranteed Constitutional freedoms, that of free speech, is being restricted with regard to the off-label utilization of pharmaceutical drugs and medical devices. So while the world of health care 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 sorely lacking to an extent that, at least relatively speaking, borders on the almost static and antediluvian. If society as a whole, and not just singular aspects of it like

medicine and health care, is to reach a suitable state in the very near-future, one elevated to an extent directly proportional to the amount of progress made since its inception in other key areas, greater attention will need to be given not only to the more effective enforcement of current laws, but also to the laws themselves. Indeed it seems nearly paradoxical that legal aspects governing how potentially life-saving medications and devices are allowed to be, or not to be, put into practice in an off-label manner are allowed to exist where lives are at stake. Nevertheless, the debate between free speech and off-label promotion continues to linger on. In the scope of things, it seems a rather reasonable goal, especially given the context, that such a 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 to the legal aspects governing it, any further discourse or dialectic on this subject, or any other for that matter, shall be rendered unnecessary.

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and Stroke Foundation of Canada, Inter American Heart Foundation, Resuscitation Council of Asia, and the resuscitation Council of Southern Africa); the American Heart Association Emergency Cardiovascular Care Committee; the Council on Cardiovascular Surgery and Anesthesia; the Council on Cardiopulmonary, Perioperative, and Critical Care; the Council on Clinical Cardiology; and the Stroke Council . Circulation .2008 ; 118 (23): 2452 – 2483.

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26. Wilhoit v. Boehringer Ingelheim Pharmaceuticals, Inc., 2009 WL 702007, at *3-4 (D. Minn. March 13, 2009)
27. Natasha Singer, Medical Papers by Ghostwriters Pushed Therapy, N.Y. Times, Aug. 4, 2009, at A1 (regarding recent allegations related to this practice).
28. 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:
29. 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.
30. 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.
31. 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.
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35. 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.
36. 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.
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40. Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989).
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Global Survey of Medical Science Liaison Job Satisfaction

By Samuel Dyer, MD, PhD | January 2016

Title

Global Survey of Medical Science Liaison Job Satisfaction

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Global Survey of Medical Science Liaison Job Satisfaction

Key Words

Medical Science Liaison, Key Opinion Leader, Job Satisfaction, Salary

Abstract

Introduction

There are numerous factors that influence job satisfaction for Medical Science Liaisons (MSLs). Identifying these specific factors may assist management in reducing turnover, improving team/individual performance, strengthening KOL-MSL relationships, and improving company performance. As of the publishing of this article, there has never been a global survey conducted on MSL Job Satisfaction. As a result, the Medical Science Liaison Society conducted a global survey of 990 respondents to gain insights into how satisfied MSLs are with their current jobs, employers, and careers across the pharmaceutical, biotechnology, medical devices and other healthcare industries.

What made this survey unique was that in addition to discovering how satisfied current MSLs are with regards to their jobs, employers and careers, the study also identified the key factors that influence overall job satisfaction. A summary of the findings was revealed during the recent annual Medical Science Liaison Society (MSL Society) Conference in Boston, September 29-October 1st, 2015.

Methods

The MSL Society surveyed 990 respondents from 61 countries. The online survey was open from July 8 to August 11, 2015 using Survey Gizmo survey software and were blinded to all authors. Both fully completed and partial surveys were counted in the results. The survey was only open to current MSLs (or equivalent title) and MSL management. Respondents were only allowed to participate one time and duplicate surveys from a single email address were not accepted. The survey results were not weighted.

Respondents were invited to participate in the survey through a range of sources including:

- Announcements in two LinkedIn groups “Medical Science Liaison & Medical Affairs Networkers” as well as “Medical Science Liaison World”
- The MSL Society newsletter
- Personal direct LinkedIn contacts

As this was not a probability-based sample, calculating the theoretical margin of sampling error is not applicable. However, as with probability surveys, it is important to keep in mind that results are estimates and typically vary within a narrow range around the actual value that would be calculated by interviewing everyone in a population. Again, as with probability surveys, on occasion the results from a particular question will be completely outside a typical interval of error.

There are many types of survey error that can limit the ability to generalize to a population. Throughout the research process, The Medical Science Liaison Society followed a Total Survey Quality approach designed to minimize error at each stage. The Medical Science Liaison Society is confident that the information gathered from this survey can be used to make important business decisions related to this topic.

Only report differences between subgroups when they are statistically significant at the 95% confidence level. While this is the industry standard for reporting results, it does mean that reported differences are simply due to chance 1 out of 20 times.

Results

The first question of the survey asked if the participant was currently an MSL or MSL management. Only those who responded as being currently in one of these two roles were allowed to continue with the survey. In the survey, 86% reported being an MSL with 14% stating they manage MSLs.

More than half of the respondents held the title of MSL (or equivalent title) (55%), while more than quarter were a Senior MSL (or equivalent title) (27%) and another 15% were in management. See Figure 1.

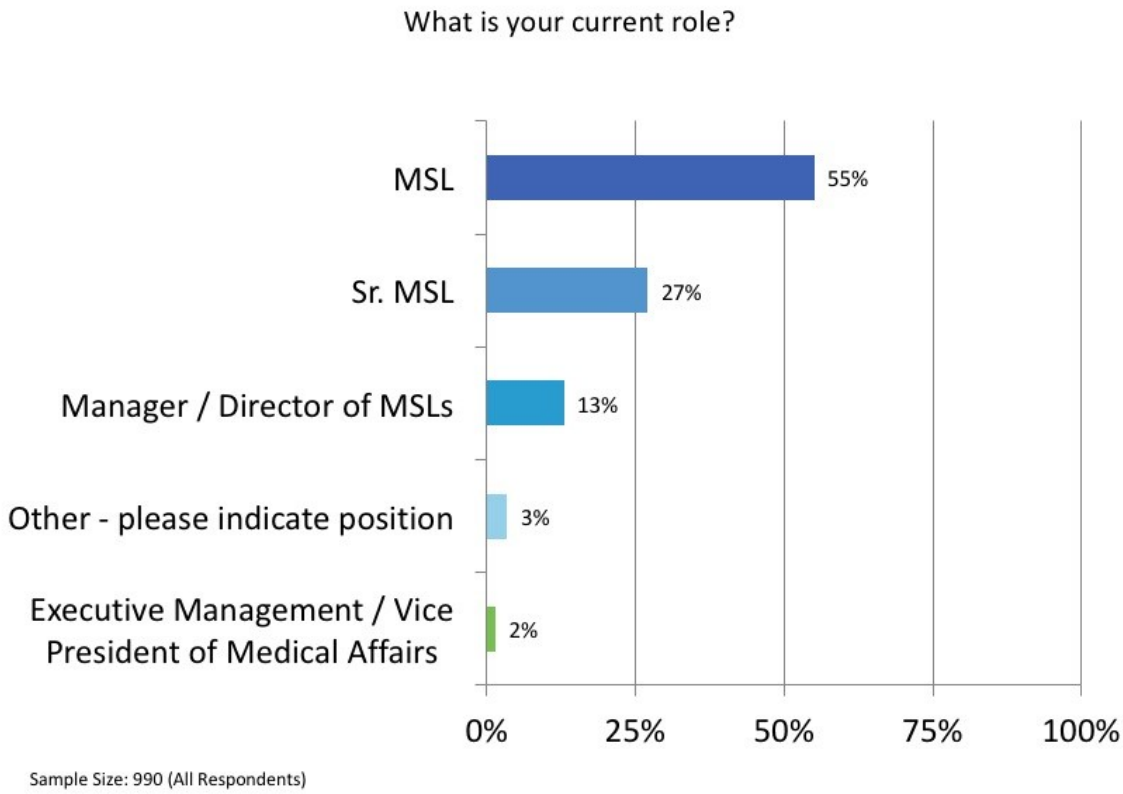

Figure 1

Almost all of the respondents in the survey report to non-commercial (medical affairs, R&D, regulatory, etc.) as their functional area (96%).

Satisfaction Index

Several factors can influence MSL job satisfaction. According to the study, 61% of participants reported being overall completely or very satisfied with their current job, with only 13% of respondents stating they were slightly or not at all satisfied with their current job. See Figure 2.

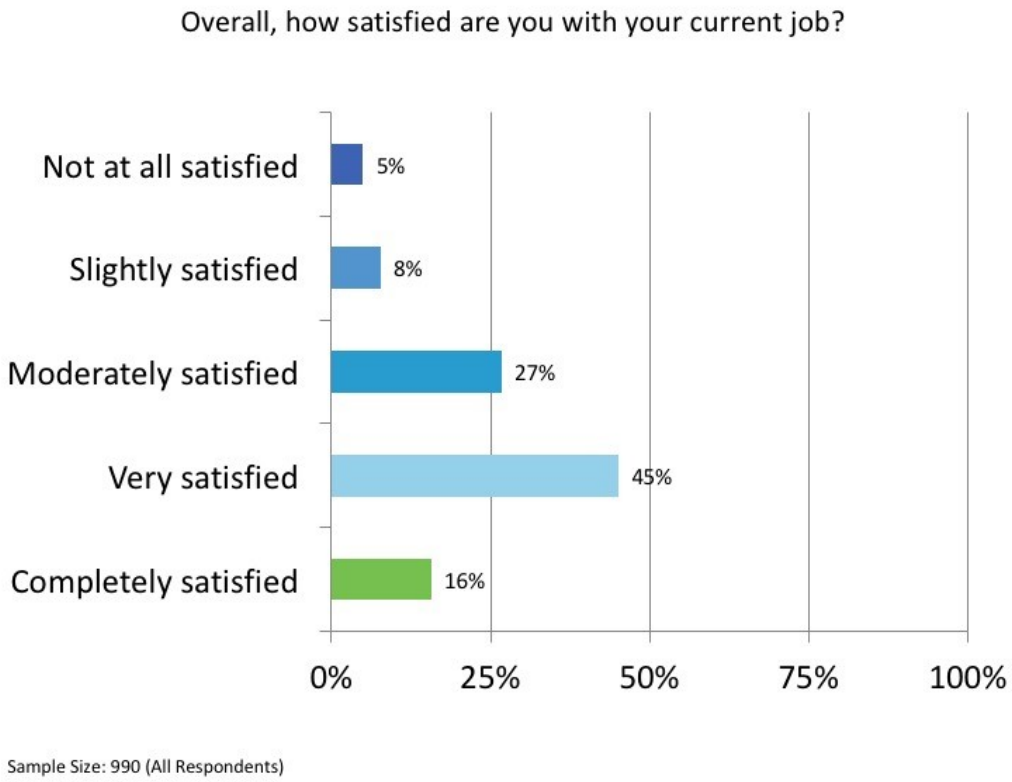

Figure 2

The same percent said that they were also very or completely satisfied with their employer. See Figure 3.

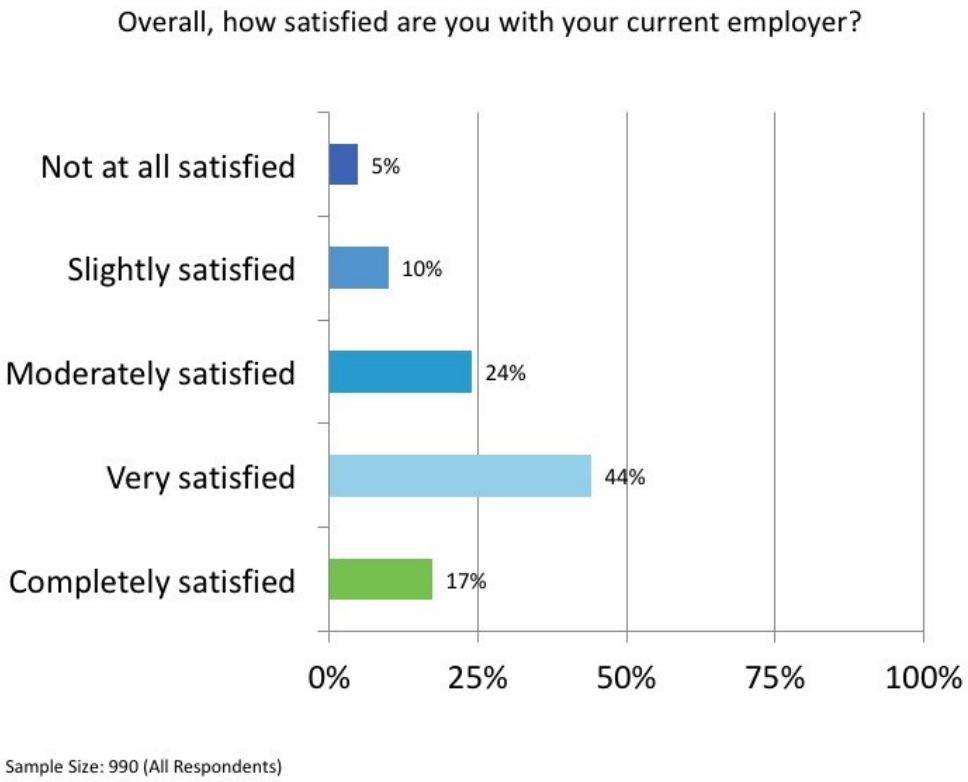

Figure 3

Another 61% were very or completely likely to recommend their current employer.

See Figure 4.

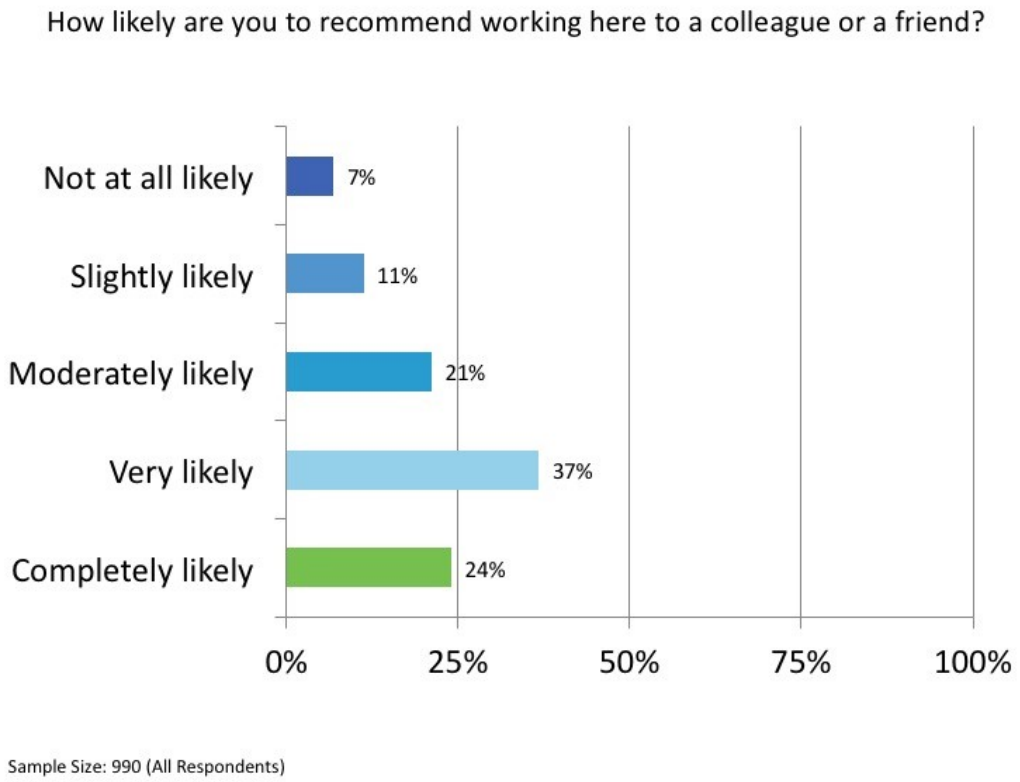

Figure 4

53% of MSLs rated their satisfaction exactly the same across all three dimensions of overall satisfaction.

These three measures of satisfaction (job satisfaction, employer satisfaction, and likelihood to recommend) were averaged together to form a Satisfaction Index, scaled from 0 to 100. Other measures that had high degrees of correlation with one another were aggregated together and then correlated to the Satisfaction Index, to determine the largest drivers of satisfaction for MSLs.

A *latent factor* is simply an aspect of MSLs' attitudes that is not directly observed but is derived from multiple measures. For instance, the Salary & Benefits Satisfaction Index is a latent factor taking into account satisfaction with many different aspects of compensation.

While salary and benefits are often seen as a key driver of overall satisfaction, in this case they explained only 51% of the shared variance with the Satisfaction Index. More important than compensation was the Self-Actualization Index (the degree to which employees can achieve their full potential), the Cultural Loyalty Index, and then two measures of the relationship with management.

Latent Factor	Correlation	Shared Variance
Self-Actualization Index	.964	93%
Cultural Loyalty Index	.939	88%
Management Information Satisfaction Index	.844	71%
Manager Relationship Index	.843	71%
Salary & Benefits Satisfaction Index	.712	51%

The closer the correlation is to 1.000, the greater the two measures correlate. However, the range is exponential, so a .900 correlation means that 84% of the variance between the two measures is shared or overlaps, while a .800 correlation means that 64% of the variance does, and a .700 correlation means that 49% of the variance is shared.

Self-Actualization Index

When questioned about their employment experience, 70% of MSLs surveyed said they are always or often proud of the work they do for their company and feel their job provides them with a sense of meaning and purpose. Almost the same amount of MSLs look forward to going to work (69%), though only 54% say they feel their company has created an environment where they can perform their best. See Figure 5.

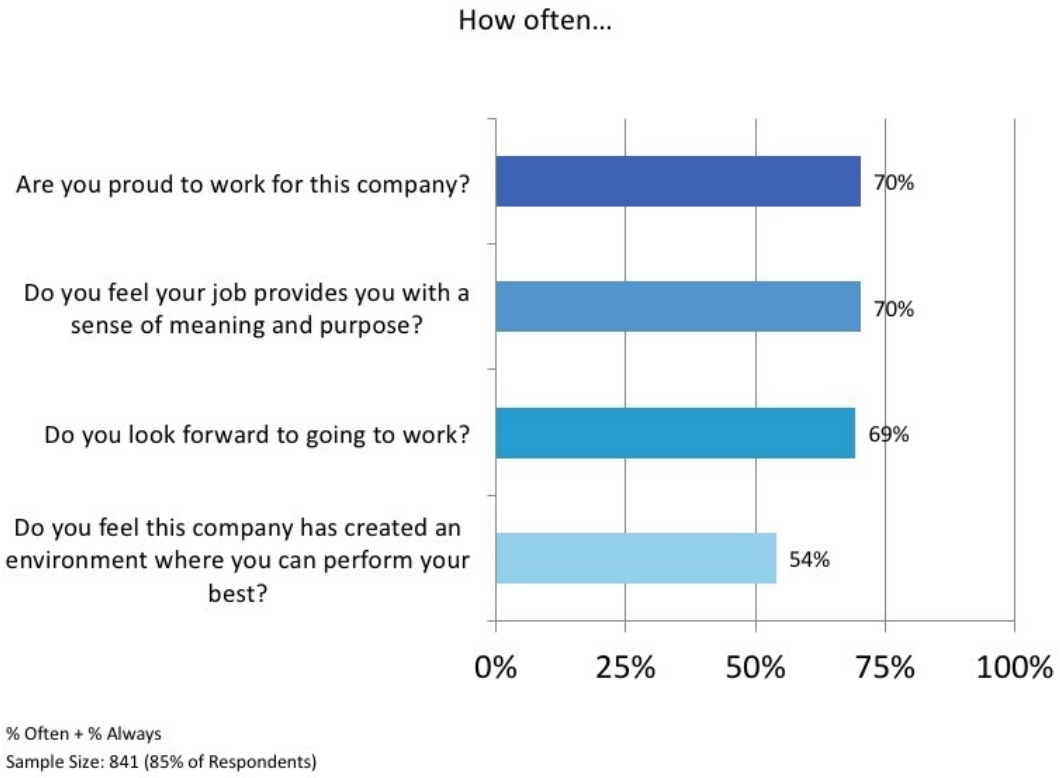

Figure 5

These four measures were combined to form the Self-Actualization Index, which has a 0.964 correlation to the Satisfaction Index and explains 93% of the shared variance between the two indices.

Cultural Loyalty Index

Culture is a key driver of overall satisfaction, yet barely half of the respondents said they were completely or very satisfied with the company culture (54%), with a quarter of them saying they were only moderately satisfied. See Figure 6.

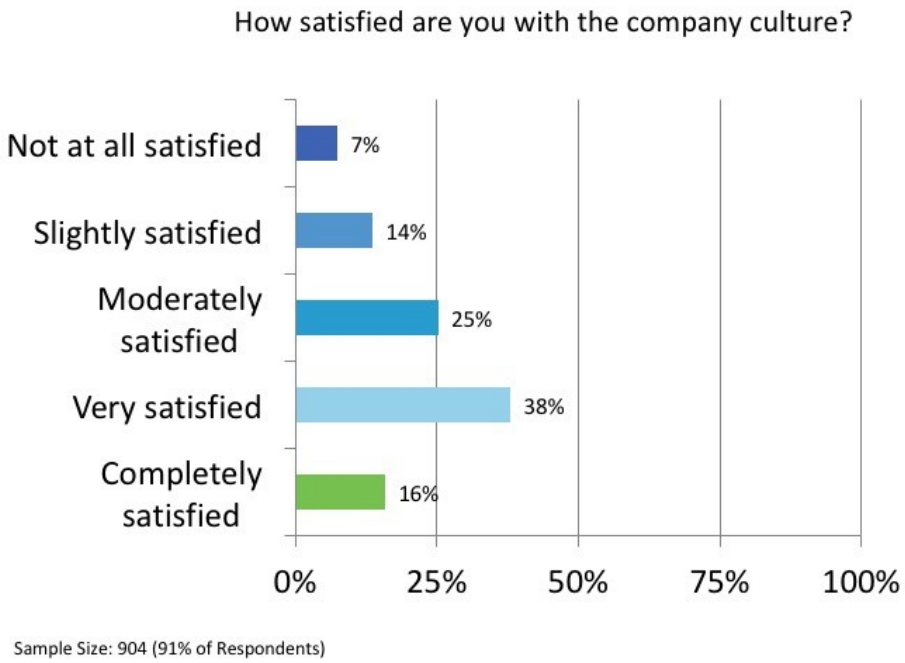

Figure 6

The majority of respondents felt their job made an extreme or significant difference in the lives of patients, with 49% reporting a significant difference and 16% reporting an extreme difference. Only 2% reported they felt they made no difference at all. See Figure 7.

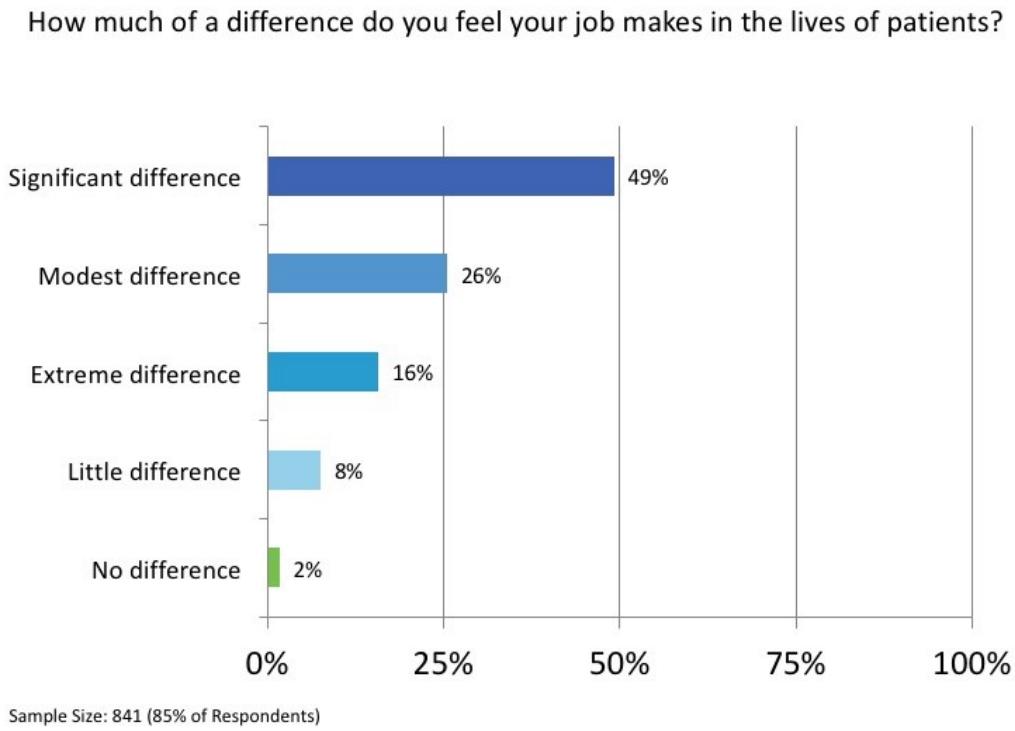

Figure 7

A majority of respondents (60%) are very or completely likely to continue their career with their company for at least two more years, while 12% are ready to leave within two years. See Figure 8.

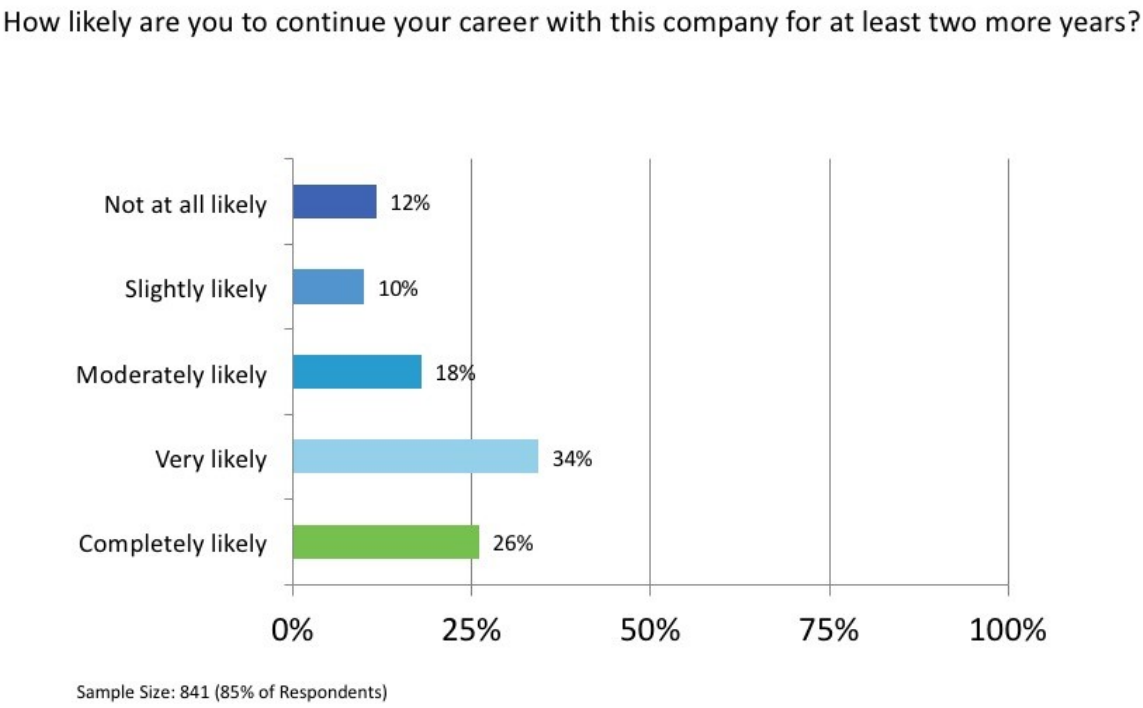

Figure 8

These measures were combined to form the Cultural Loyalty Index, which has a 0.939 correlation to the Satisfaction Index and explains 93% of the shared variance between the two indices.

Management Information Satisfaction Index

Half of respondents (49%) are very or completely satisfied with the information they receive from management on what is going on with their team or within their department, though 6% said they were not at all satisfied. See Figure 9.

Figure 9

Only 44% said they were completely or very satisfied with the information they received on what was happening with the company, while 34% said they were moderately satisfied. See Figure 10.

Figure 10

These measures were combined to form the Management Information Satisfaction Index, which has a 0.844 correlation to the Satisfaction Index and explains 71% of the shared variance between the two indices. Clearly, this is an easy way that employers can improve overall satisfaction, simply by communicating more.

Manager Relationship Index

Knowing what is needed in order to advance their career is important to MSLs, yet only 45% said they completely or mostly understand what is expected of their career advancement at their company. See Figure 11.

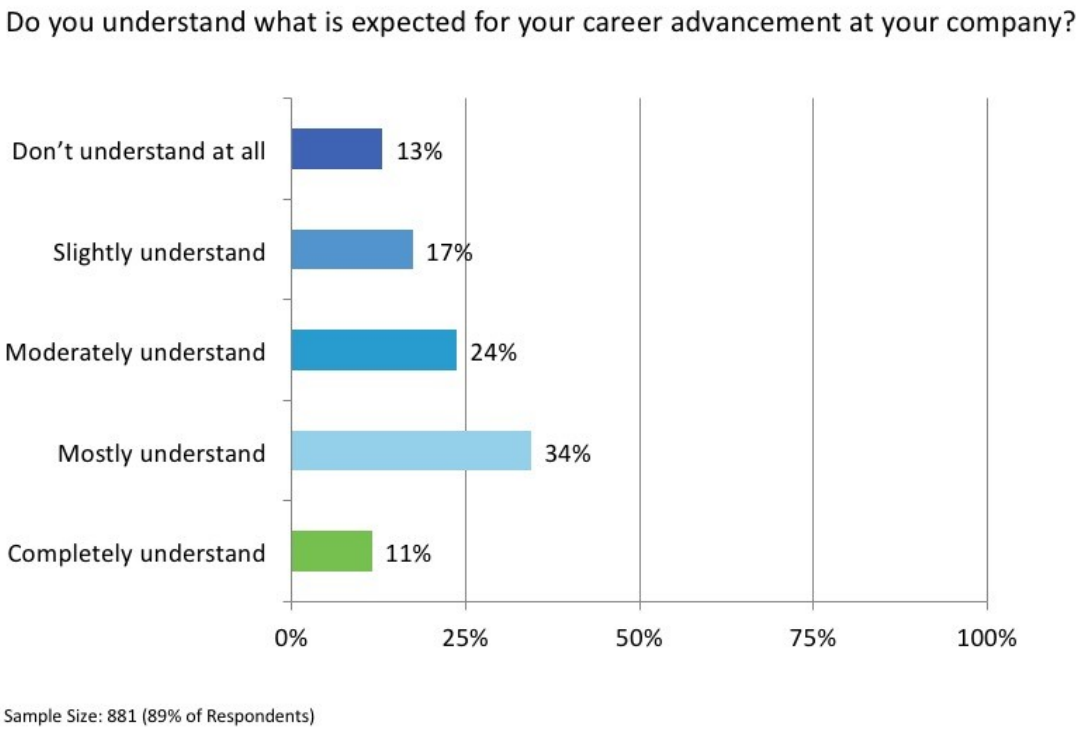

Figure 11

Ironically, those with more tenure at an organization are less likely to report that they understand career advancement. Of those at their current employer 6 to 10 years, 25% also selected 'Mostly understand' vs. 41% there less than 1 year and 35% of everyone else.

Nearly three quarters of MSLs said that their manager acknowledges when they do their work well (74%), with 62% saying that their manager's ability to help them develop to their fullest potential is excellent or good. See Figure 12.

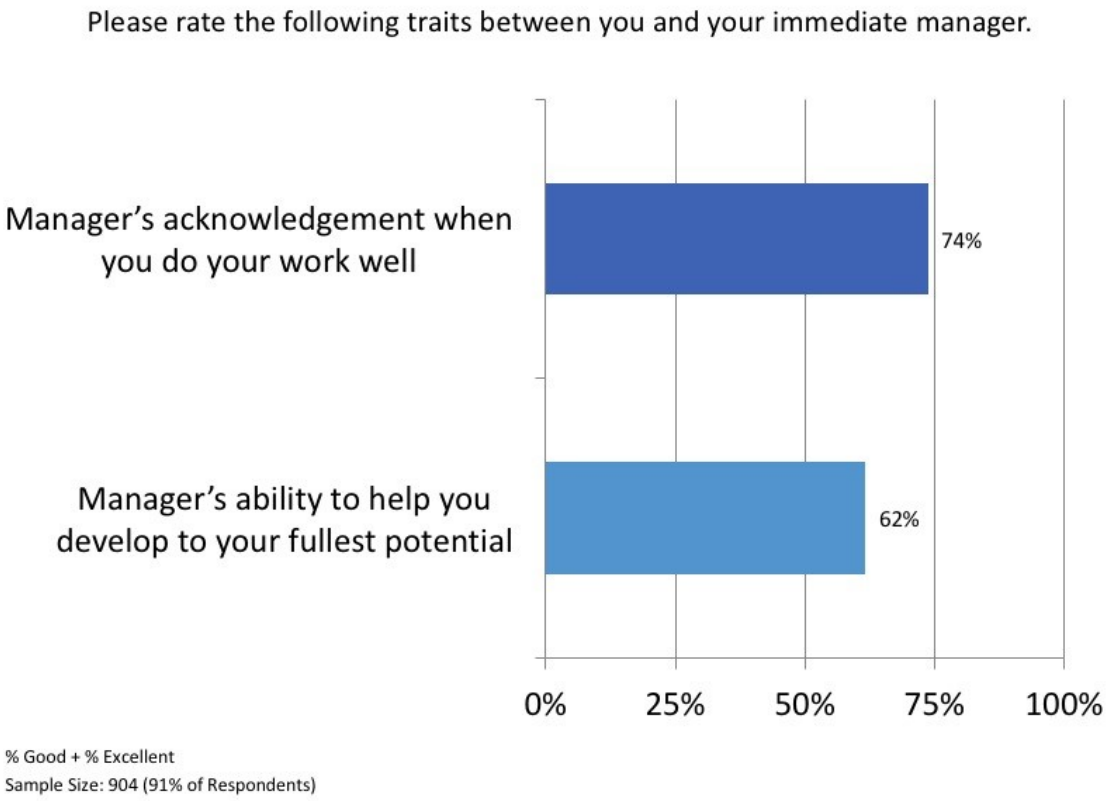

Figure 12

When it comes to trust, 72% of MSLs said that they completely or mostly trust what their manager tells them, with 4% saying that they didn't at all. See Figure 13.

Figure 13

These measures – career advancement, manager's acknowledgements, manager's development ability, and manager trust – were combined to form the Manager Relationship Index, which has a 0.843 correlation to the Satisfaction Index and explains 71% of the shared variance between the two indices.

Salary & Benefits Satisfaction Index

Salary and benefits are clearly important factors in successfully recruiting and retaining the best MSL talent but they also contribute overall to job satisfaction. Interestingly retirement benefits and overall pay were the two lowest rated aspects of their salary and benefits that respondents were completely or very satisfied with (46% and 48% respectively) while Vacation/holiday or paid time off saw the highest satisfaction from MSLs (57%). See Figure 14.

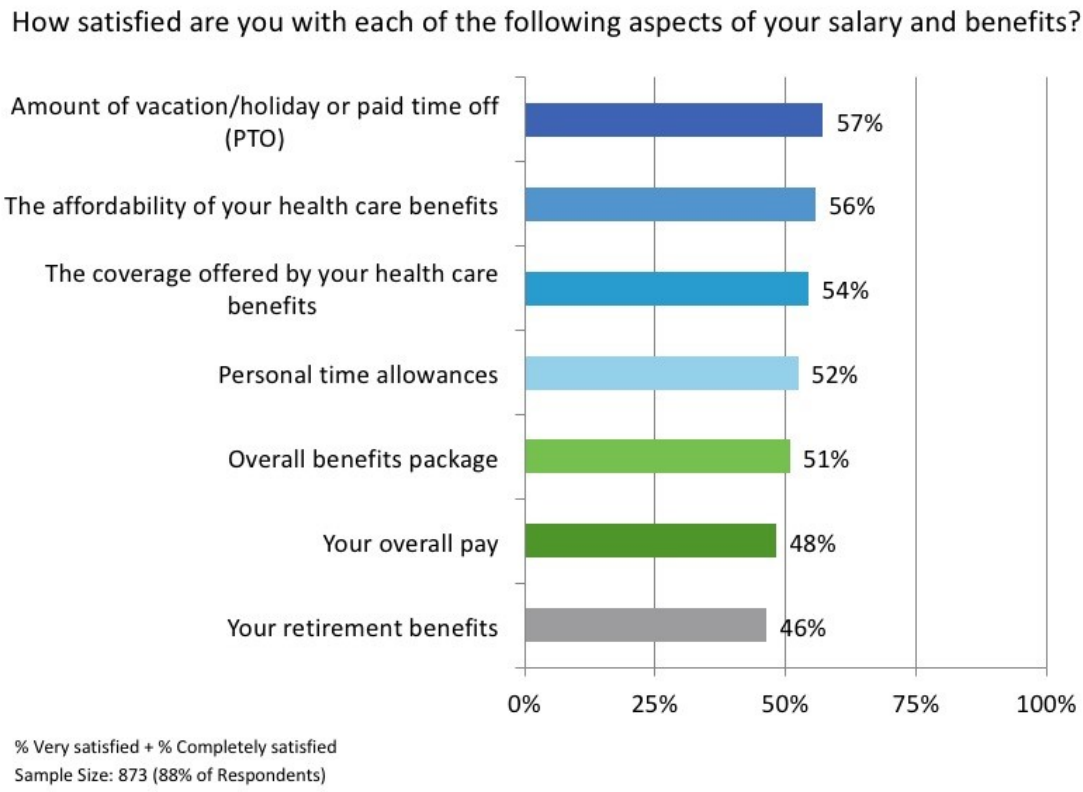

Figure 14

These measures were combined to form the Salary & Benefits Satisfaction Index, which has a 0.712 correlation to the Satisfaction Index and explains 51% of the shared variance between the two indices.

KOL Relationship Management

Less than half of the respondents said they felt the number of relationships they are expected to manage with KOLs, Thought Leaders, and physicians were just right (47%), while 43% stated they felt they had too many. See Figure 15.

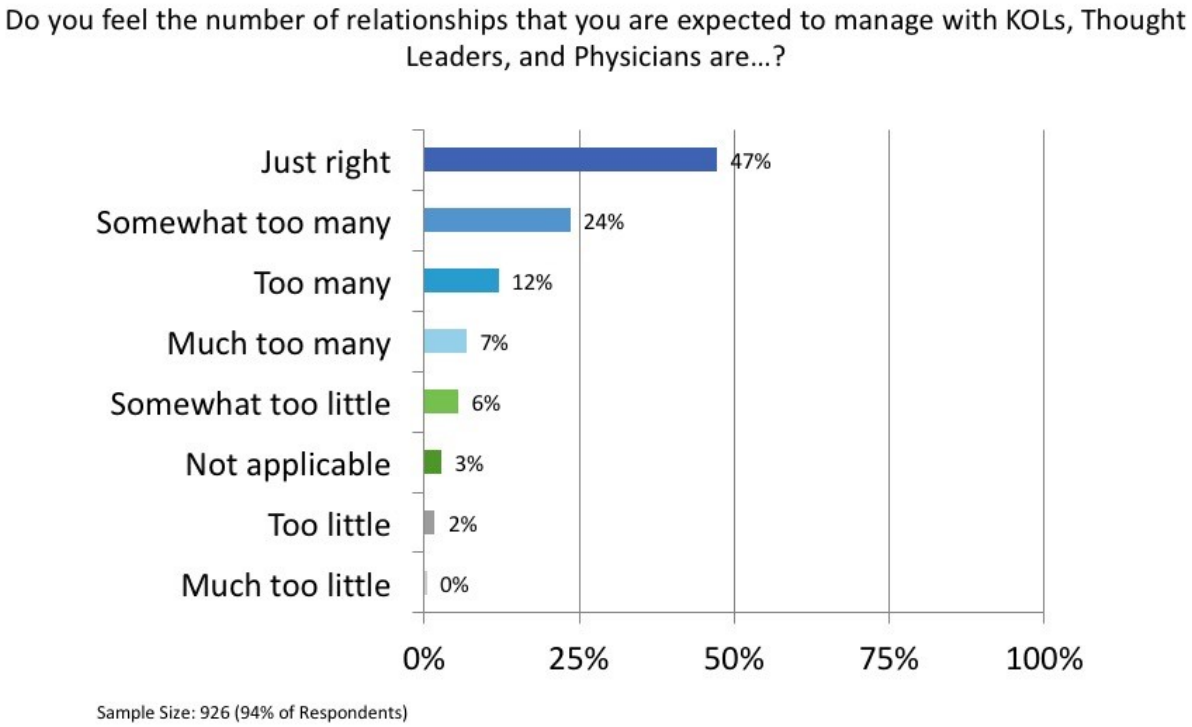

Figure 15

Training and Career Development

Despite the majority of respondents being satisfied with their job, fewer are satisfied with their professional development. Training is an important aspect for MSL success. Only 49% said that they were completely or very satisfied with the ongoing training their company has provided to them, 50% with the initial (onboarding) training about disease state, therapeutic area, and/or product that the company provides, and only 42% with funding for ongoing external training and seminars to help with their career development. See Figure 16.

Figure 16

Strikingly, the majority of MSLs also reported that they are not offered a formal career growth plan within their company. See Figure 17.

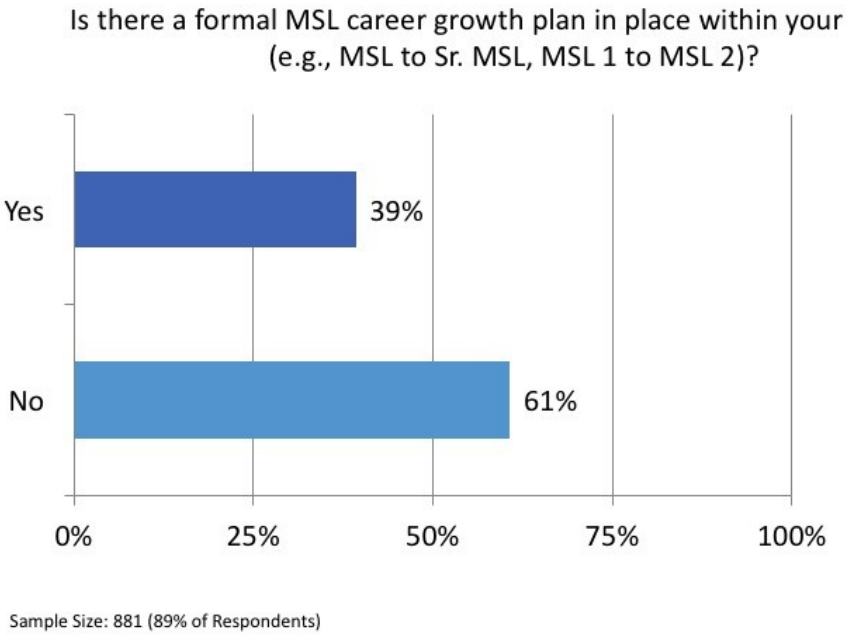

Figure 17

Career Change

Even the most satisfied of employees may be considering a career or company change. As to why one would consider a change, the three most selected choices were lack of or no opportunities for career advancement/promotion (41%), career change within industry (39%), and inadequate salary and benefits (36%). See Figure 18.

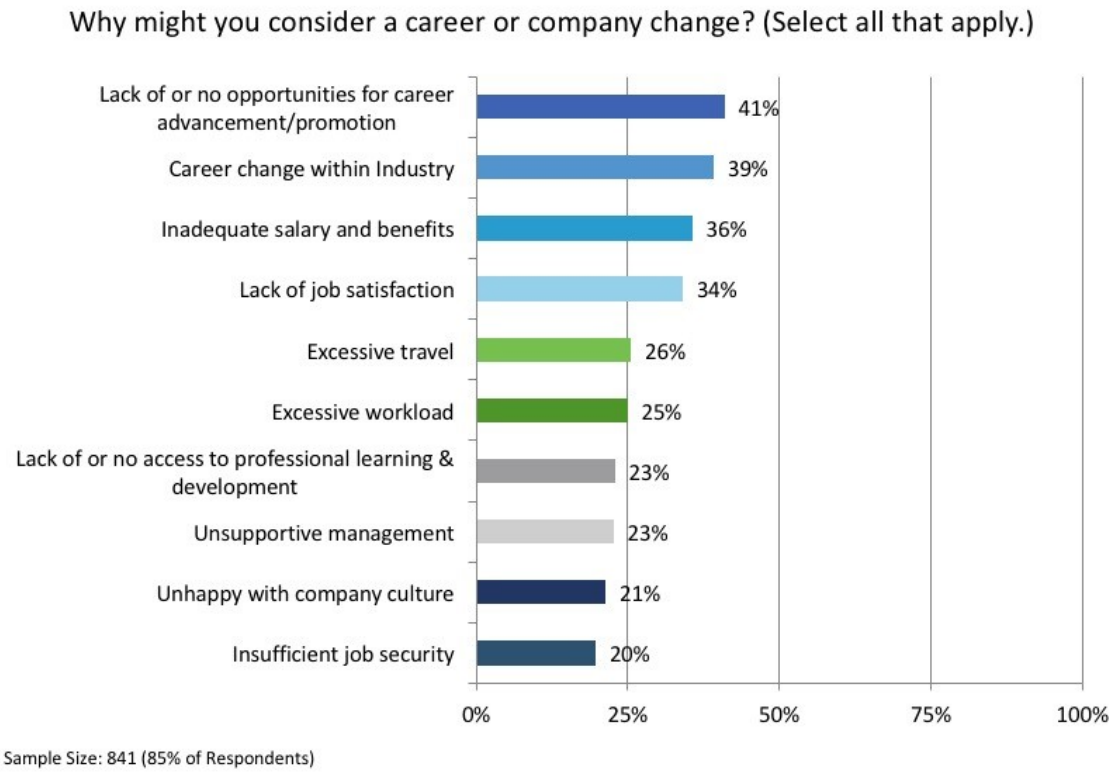

Figure 18

Conclusions

This survey represents the first study of global MSL Job Satisfaction and serves as an industry baseline for measuring current levels of job satisfaction across the industry. This study highlights that there are numerous factors that influence job satisfaction for Medical Science Liaisons (MSLs) detailing that the issue is quite complex in nature, and will require a cross functional approach to improving the current perception of today's MSLs within some organizations. Despite the majority of respondents being satisfied with their job and company, fewer are satisfied with other aspects of their careers including their professional development, training and having a clear understanding of career progression. Some may consider leaving their current job as of a lack of or no opportunities for career advancement/promotion. This outcome suggests that traditional methods for career advancement through vertical promotion are not adequate, and as such pathways for advancement such as increased responsibility that may not result in a title change may be helpful in MSL retention. Each of these strategies, however, requires an engaged leadership team and human resources function to create a culture of long term sustainability, associated engagement, and retention.

The results of this study may be utilized by management to help reduce MSL turnover, improve team/individual performance, strengthen KOL-MSL relationships, and ultimately improve the human capital aspects of the MSL function.

Acknowledgments

Thanks to Alexander Tolmachev, MD, Senior Manager, Medical and Regulatory Projects Takeda, Russia and Kumaran Krishnan, MBA, Medical Affairs Centre of Excellence-Europe Sanofi, UK who both provided insight and expertise with the creation of the questions for this survey.

References

2015 Global Survey of Medical Science Liaison Job Satisfaction, Medical Science Liaison Society, 2015.

Additional Resources

The full 180+ page MSL Job Satisfaction Report, which reveals details of these findings and other insights, is available for free for all members of the MSL Society under the resource section of the society website www.themsls.org.

About the author:

Samuel Dyer, MD, PhD

Dr. Samuel Dyer is the CEO of the Medical Science Liaison Society and has over 25 years of international MSL experience. During his career, he has managed MSL teams and operations in over sixty countries across the United States, Canada, Europe, Africa, the Middle East, Australia, and New Zealand. He has facilitated the successful launch of pharmaceutical and medical device products for both Fortune 500 pharmaceutical companies and small biotechnology companies.

Dr. Dyer has coached, interviewed, and reviewed the CVs of countless aspiring MSLs. His insights and guidance have resulted in hundreds of aspiring MSLs successfully breaking into their first roles.

While leading the MSL Society, he has conducted MSL training programs for over 75 pharmaceutical, biotechnology, and medical device companies in more than 15 countries. Dr. Dyer has also written extensively on the Medical Science Liaison profession, including numerous published articles, benchmark studies, and reports. He has been the keynote speaker and moderated numerous international conferences on various MSL–related topics, including creating teams, management, MSL training, proper utilization of MSLs, global trends, and the KPIs and metrics used to measure MSL performance. Dr. Dyer has also served as a resource and consultant on several MSL–related projects for several organizations, including McKinsey & Company and Bain & Company.

Dr. Dyer has an MD from Washington University (Health & Science) School of Medicine, a PhD in Health Sciences from Touro University, a Master's degree in Tropical Biology (where he studied in the Amazon) from Southern Illinois University Edwardsville, and a Bachelor's degree in Biology from the University of the State of New York. Dr. Dyer also completed a certificate program for Executive Leadership and Strategy in Pharmaceuticals and Biotechnology at the Harvard Business School.

Dr. Dyer is the author of the multi-award-winning and Amazon #1 Best Seller, *The Medical Science Liaison Career Guide: How to Break into Your First Role* (https://amzn.to/4aoYcZp). The book is the first and only step-by-step guide on how to break into the MSL profession and it has received multiple prestigious awards, including:

- 2024 Winner of the American Legacy Book Awards in the Business: Careers category.
- 2024 "Gold Award" Winner – Literary Titan Book Awards in the Career category.
- 2023 "Best Book" Winner – Pinnacle Book Achievement Award in the Career Development category.

He is also the author of the *Medical Science Liaison Job Application Tracking & Interview Self-Evaluation Journal* (https://amzn.to/49n6MGR).

Welcome from the Chairman of the Board

By Samuel Dyer, MD, PhD | January 2016

Dear Colleagues:

It was great seeing many of you at the recent annual U.S. conference held in Cambridge, MA. This year's conference was attended by over 100 Medical Science Liaison professionals, managers, and other key stakeholders from 10 countries. Over the last two months, the MSL Society has been hard at work behind the scenes making the final preparation to launch the industry's first and only professional board certification for the professional Medical Science Liaison. This new and exciting initiative will launch on soon with registration opening for all eligible candidates to complete their application online. The exam is multiple choice and covers the cognitive domains necessary for competency as a Medical Science Liaison. More information will be available soon on our website: www.themsls.org

Regulations from the US Food and Drug Administration continue to become more stringent. Given the evolving regulatory

landscape that guides the activities of pharmaceutical, biotechnology, and medical device companies, the MSL Society will be launching a series of new professional position statements intended to serve two purposes:

- Guide the conduct of the Medical Science Liaison and prevent undue influence by commercial interests, sales compensation, etc.
- Self regulate the profession by creating proactive guidance statements about key issues relevant to the professional Medical Science Liaison such as off label promotion, scientific information dissemination, and more.

These position papers will be available to all MSL Society members and authored by an expert panel of subject matter experts consisting of frontline Medical Science Liaisons, middle managers, Executive Leaderships, and Regulatory/Legal colleagues. It is our goal that these documents will serve as instrumental tools in each Medical Science Liaison's daily practice within their organization. The first position paper will be published in the January 2016 issue of *THE MSL: The Journal of the Medical Science Liaison Society*.

Finally, the MSL Society is launching a new professional advancement and recognition program in early 2016: The MSL Fellows Program resulting in the designation FMSL. This terminal designation is only awarded to those in profession that have not only met certain academic and professional experience criteria, but more importantly have made documented and ongoing contributions to the Medical Science Liaison profession outside of their traditional professional responsibilities. More details on this exciting program will be launched on the MSL Society website shortly after the first of the year.

Thank you for your ongoing support of the MSL Society and your commitment to advancing our profession through peer reviewed publications, board certification, and professional advancement through the new Fellows program.

Sincerely,

Samuel Dyer, MD, PhD
Chairman of the Board
Medical Science Liaison Society