AMERICAN MEDICAL WRITERS ASSOCIATION
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Volume 38 Number 4 / Winter 2023

JOURNAL

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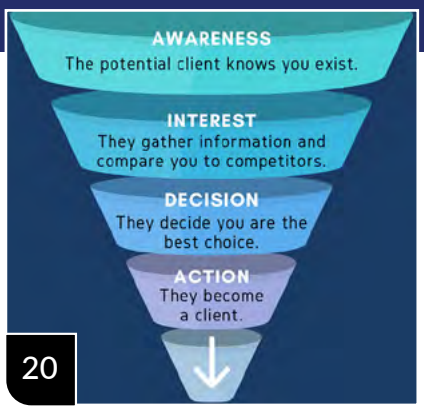

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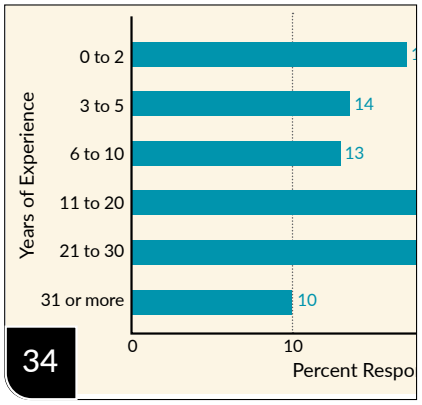

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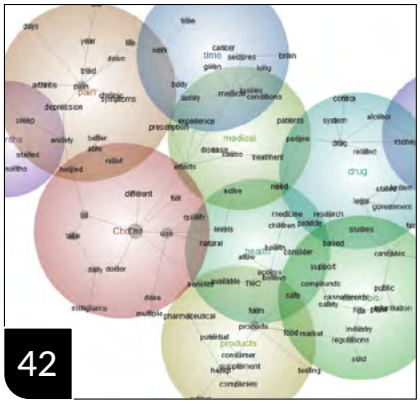

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FROM THE GUEST EDITOR

Preserving Ethics in a Not So Ethical World

Julie Ravo / Medical Writer, Franklin Lakes, NJ

Ethical principles can be traced as far back as the ancient philosophers, including Plato and Aristotle, who believed in virtue as a guide for ethical action, and Kant, who developed the concept that obligation instructs us how to behave.[1] The terms "professional ethics" and "medical ethics" were created by English physician Thomas Percival in 1803, which led to the adoption of the first code of ethics by the American Medical Association in 1847.[2]

Today, many corporations and organizations have established a code of ethics for employees and members. These codes provide a guide on what to do, as well as what not to do, in a given situation. Adherence to these values strengthens the company culture, minimizes risk, and helps protect the company's reputation. In addition to potential damage to image and public trust, the financial consequences of unethical behavior can be extensive. One medical device manufacturer and its subsidiaries have paid more than $60 million in settlements due to kickback and fraud allegations.[3] Even though many organizations have established codes of conduct for their associates, they do not eliminate the potential for misconduct. In 2020, the Harvard Business Review reported the results of a national survey on business practices conducted with more than 14,500 employees across many industries. Nearly 1 in 4 survey respondents felt pressured to do things they knew were wrong.[4]

Two articles in this ethics-themed issue present some ethical challenges for medical communicators. The first article by Blair Hesp and Jonathan Lee discusses how differences in cultural contexts can alter the interpretation and application of ethical publication practices in the Asia-Pacific region. This topic expands on the articles published in the previous themed issue of the *AMWA Journal* on global medical communication. However, addressing cultural differences can be particularly challenging because many of these engagements are conducted virtually. The authors provide recommendations on effective navigation of cultural differences to ensure that contributions are included from all stakeholders and engaging with colleagues in other regions to develop culturally appropriate processes that can strengthen working relationships and expedite project completion.

Continuing medical education (CME) is an essential component of ongoing professional development for health care providers. However, industry support of CME has raised concerns about the integrity of the content. The second article by Eve Wilson explores some of the requirements intended to prevent industry bias in continuing education (CE)/CME. Medical writers may play a key role in the development of CME materials; practical steps are presented for medical writers to ensure that CE/CME content is fair, balanced, unbiased, and accurate.

I wish to thank the authors of these articles for their time and efforts. I also encourage any feedback from AMWA members on any personal ethical challenges they've encountered in their everyday interactions.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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ISSN 2163-5315

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THEME ARTICLE

Embracing Cultural Differences to Ensure Ethical Publication Practices

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ABSTRACT

Ethical publication practices apply universally, but differing cultural contexts can alter the interpretation and application of guidelines. In particular, collaborating with colleagues and authors in the Asia-Pacific region can sometimes be confusing and frustrating when attempting to align expectations between all parties involved in medical writing projects. Engaging with colleagues in other regions to develop flexible, culturally appropriate processes can help strengthen working relationships, expedite project completion, and adhere to publication best practices.

Research into international differences in adhering to publication ethics guidelines has historically suggested that standards in the Asia-Pacific region (APAC) are lagging behind those in North America and Europe.[1] However, recent data suggest that awareness and adherence to the principles of publication ethics is increasing in APAC.[2] In addition, there are a number of challenges regarding the application of international guidelines in APAC, including limited engagement with regional representatives and relatively scarce resources to support regional research and guideline development.[3] Despite this, a number of organic efforts have been initiated within APAC to better understand publication practices and to bridge differences in expectations between regions.[1,4-9] This is similar to efforts made within APAC to adapt international medical treatment guidelines to account for the specific circumstances in APAC compared with other regions.

THE DIFFICULTY IN ALIGNING EXPECTATIONS ACROSS CULTURES

Independent guidelines developed to improve ethical publication practices and industry internal standard operating procedures that use these guidelines as a framework are often applied on the basis of regional differences not materially impacting their application. Accordingly, many of the conventions surrounding how ethical publication practices and authorship are applied when developing English-language medical publications have been developed in predominantly English-speaking high-income countries.[3] For example, every author is generally expected to openly share documents illustrating proposed changes and detailed comments with the authorship group and other stakeholders. Debate is expected, and encouraged, to improve the quality of the publication, and the opinions of individuals are considered on an equal basis. In addition, although communication has traditionally been via formal written correspondence (eg, email), the convenience of video calls also means that real-time verbal discussions between authors are now common.

Some of these practices can be inconsistent with cultural expectations and norms in APAC, so there is a risk that important clinical insights that could be offered by authors and other stakeholders may be missed if stakeholders are unable to fully articulate their ideas and/or feel hesitant to comment, especially speakers of English as a second language. Likewise, alternative forms of communication that are prevalent in APAC, whether they be verbal feedback provided one-on-one during in-person meetings or via messaging apps (eg, WeChat), may not strictly align with standardized procedures for commenting or maintaining formal records that are applied in Western countries.[8]

Here, we describe the cultural and communication norms in APAC and provide some recommendations on how these can be effectively navigated to ensure that important insights from all stakeholders are not overlooked.

THE CURRENT LANDSCAPE

Most discussions regarding medical publications are conducted exclusively in English, which poses challenges for communicating complex ideas for those who do not speak English as a first language. Furthermore, there is a growing expectation to engage in situations that can be challenging for non-native English speakers from APAC, such as video conferences, in which it can be difficult to follow comments from numerous people who are often speaking quickly and with different accents.

In particular, East Asian cultures (eg, Japan, China, Korea) tend to favor consensus-seeking and collectivism over individualism. So, for example, although interruptions can be routine and tolerated in video conferences,

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many participants from APAC will default to agreeing with or approving statements from others to out of fear of embarrassing themselves or their colleagues and to avoid any potential conflict. Likewise, there can be a tendency for people from some parts of APAC to be careful to defer to more senior colleagues, especially in a public setting. Unwritten cultural protocols regarding marks of respect and how to politely interact with colleagues in APAC can also make it difficult for native English speakers to correctly interpret comments and remarks. Unless you are very familiar with the person's culture, this can be a source of substantial confusion and frustration when working with colleagues and authors from APAC.

EFFECTIVELY NAVIGATING LANGUAGE AND CULTURAL DIFFERENCES

When engaging people in APAC professionally, we recommend consulting with someone with substantial local knowledge before initiating a project. People with regional expertise are generally eager to help their peers navigate cultural sensitivities and may help you avoid potential pitfalls. The mere act of seeking guidance in advance is likely to be widely appreciated.

Allowing for extended review times and less formal methods of communication that the local team and authors are familiar and comfortable with, such as WeChat in China, may be necessary. Likewise, utilizing the support of a person who can speak an author's native language or meet with them in person can improve the volume and quality of comments. One-on-one engagement, in person or via email, can also facilitate effective communication by offering circumstances for individuals to speak freely without fear of disrespecting colleagues. When communicating in a group setting, requests for feedback should be individualized before being communicated in a consolidated, anonymized fashion.

NOVEL CHALLENGES IN 2023

The increasing prevalence of plain-language summaries and enhanced content offers new opportunities for engaging APAC, but their limitations still need to be understood. For example, *Lancet Global Health* invites authors to submit translations of the abstract of an accepted manuscript. However, most journals do not offer such broad multilingual opportunities, so most plain-language summaries need to comprise wording, imagery, and context that can survive translation across languages and cultures. Intended messaging can be misinterpreted or literally lost in translation.

Artificial intelligence is also rapidly evolving, and as of mid-2023, its utility in medical writing has not yet been fully established. Although likely offering two-way benefits for communicating across cultures and languages, the limitations of artificial intelligence in writing and translating need to be remembered.

CONCLUSION

Considering cultural and communication differences is important when working with authors outside of North America and Europe. Ensuring full access to the valuable insights of authors who are speakers of English as a second language, such as those from the APAC region, can improve the quality of medical writing when approached in a culturally appropriate manner, ultimately benefiting the patients we strive to support through our publications.

Author declaration and disclosures: *Jonathan Lee is an employee of Takeda Pharmaceuticals International AG–Singapore Branch, is a sponsor of clinical research performed in APAC, holds Takeda stock, and is also the current Asia-Pacific Trustee on the International Society of Medical Publication Professionals (ISMPP) Board of Trustees. Blair Hesp is the owner of a company offering medical communication services to pharmaceutical, medical device, and diagnostics industries and authors within APAC, including publication planning consultancy and professional medical writing support, and is also a member of the ISMPP Asia-Pacific Collaborations Outreach Committee. The ideas presented are those of the authors and not intended to represent those of their employers or ISMPP.*

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THEME ARTICLE

Can Industry-Funded CE/CME Be Unbiased? Current Insights on an Old Question

Eve J. Wilson, PhD, FACEHP / Medical Director, PlatformQ Health, Needham, MA

ABSTRACT

Over the years, multiple reports and editorials have asserted that continuing education/continuing medical education (CE/CME) that is funded by the pharmaceutical or device industry is biased in favor of the funder's product(s). But starting in the early 2000's, several stakeholder organizations began establishing guidance to prevent such bias, and currently there are many protections in place. In particular, the Accrediting Council for Continuing Medical Education (ACCME), the accrediting body for all national organizations that provide CE/CME, established and continues to update specific standards to prevent bias, and all ACCME-accredited organizations must comply with these and other standards to maintain their accreditation in good standing. A careful review of the literature has identified just a few studies that explore the question of bias in CE/CME, all published from 2010 – 2012. None of these studies found evidence of bias in CE/CME, and no empirical studies on the topic have since been published. Thus it seems that the protections in place are working, although more rigorous and definitive research is needed. Nevertheless, continued vigilance is paramount, and medical writers play an important role in providing oversight of CE/CME by ensuring that content they develop is fair and unbiased, as well as accurate and intended to promote optimal patient care.

There is a widespread and persistent assumption that continuing education/continuing medical education (CE/CME) that is supported via educational grants from pharmaceutical or device companies is biased toward the supporter's product or products. But is the assumption fair, and is there evidence to support it? What do clinician learners have to say? This article explores requirements intended to prevent industry bias in CE/CME, published research on bias in CE/CME activities, and practical steps medical writers can take to ensure that CE/CME content is accurate and objective.

CURRENT ACCREDITATION REQUIREMENTS FOR PREVENTING COMMERCIAL BIAS

For many years there have been layers of protections to prevent commercial bias in CE/CME from various stakeholders in CE/CME. Protections currently in place include codes of ethics (from the Pharmaceutical Researchers and Manufacturers of America, the Advanced Medical Technology Association, and the American Medical Association),[1-3] compliance guidance from the Department of Health and Human Services' Office of Inspector General,[4] and accreditation requirements from the Accrediting Council for Continuing Medical Education (ACCME).[5] With regard to CE/CME content, ACCME's *Standards for Integrity and Independence in Accredited Continuing Education* offers the most detailed guidance.[5]

The ACCME is the accrediting body for all national organizations that provide CE/CME. It has a long history of concern about commercial influence in CE/CME. The first ACCME standards were released in 1992;[6] major revisions were released in 2004 and again in 2020. The revisions have (among other priorities) progressively better defined and further restricted industry influence. The most current standards focus on 5 aspects of CE/CME funding, development, and delivery (Table 1); the most relevant for development of CE/CME content are standards 1 and 2.

Table 1. The Accreditation Council for Continuing Medical Education's Standards for Integrity and Independence in Accredited Continuing Medical Education[5]

Standard 1	Ensure content is valid.
Standard 2	Prevent commercial bias and marketing in continuing medical education.
Standard 3	Identify, mitigate, and disclose relevant financial relationships.
Standard 4	Manage commercial support appropriately.
Standard 5	Manage ancillary activities offered in conjunction with commercial support.

ISSN 2163-5315

The content validity standard (Standard 1) holds accredited providers responsible for ensuring their education is fair and balanced and supports safe and effective patient care. Standard 1 specifies that research discussed in CE/CME must "adhere to generally accepted standards of experimental design, data collection, analysis, and interpretation" and that recommendations for patient care must be "based on current science, evidence, and clinical reasoning."[5]

Standard 2 requires that all decisions regarding planning, delivery, and evaluation of CE/CME be made free of influence or involvement from "ineligible companies" (formerly called "commercial interests"). Ineligible companies are defined as those "whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used on or by patients." Importantly, ineligible companies also cannot recommend, or even suggest, names of faculty for CE/CME programs.[5]

PERCEPTIONS OF BIAS AMONG CLINICIAN LEARNERS: WHAT DOES THE RESEARCH SHOW?

To date, numerous reports and editorials have asserted that commercial support introduces bias in CE/CME; some have even called for a total ban.[7-9] But none cite empirical evidence to support bias due to commercial support—perhaps because so few studies have systematically examined the issue. A careful literature search turned up only 4 studies conducted after 2004 (when ACCME first released more rigorous standards) that relied specifically on feedback from clinicians participating in CE/CME.

One study examined 95,000 evaluation responses across 346 CE/CME activities held in 2007 by the Cleveland Clinic Center For Continuing Education.[10] The analysis found that a mean of 98.4% participants responded "yes" (vs "no") to a question about whether the activity was "satisfactorily free" of commercial bias, and a mean of 97.2% participants responded with "excellent" or "good" to the question about the degree to which the activity was free of commercial bias. When analyzed based on commercial support, activities were considered free of commercial bias by 98.5% of respondents for activities with a single support source, 98.3% of respondents for activities with multiple support sources, and 98.0% of respondents for activities with no commercial support.

A second study examined evaluation responses for 213 accredited, live educational courses offered by the University of California at San Francisco from 2005 to 2007.[11] About 33% of courses had no commercial support; the others had varying levels of support. This study found that a median 97% of participants perceived no commercial bias (median number of participants per program was 132). Moreover, no associations were observed between the degree of perceived bias and the extent or absence of commercial support.

A third study looked at perceived bias in evaluations from 1,064,642 physician participants in 3,137 Medscape online CME activities, of which 28% were supported by industry.[12] Evaluations asked whether the activity was "presented objectively and free of commercial bias," with these answer choices: strongly agree, agree, no opinion, disagree, or strongly disagree. Overall, just 0.63% of respondents disagreed or strongly disagreed with the statement; that rate was slightly higher (0.84%) for commercially supported activities and slightly lower (0.48%) for those with no commercial support.

Interestingly, the fourth study examined perceptions of bias in live CME programs that received *no* commercial support, held in 2006, 2007, and 2010.[13] More than 1,500 attendees were asked whether they thought commercial support influenced content selection for the overall program and for individual lectures. From 6% to 9% responded "yes" or "somewhat" across programs; of those who rated a program as biased, about 75% also rated one or more lecture as biased. These findings speak to a nuance well beyond the scope of this article—specifically, that clinicians may perceive commercial influence as something beyond just commercial support.

Based on these findings, it seems fair to conclude that at least from clinicians' point of view, commercial bias in CME is quite low and independent of commercial support. However, more—and more definitive—research is needed. In the meantime, it remains crucial to safeguard against bias. All those involved in content development, including medical writers, must be aware of that potential and work to mitigate the risk.

PRACTICAL STEPS FOR MEDICAL WRITERS

Perhaps the 2 most important (and interrelated) concepts for medical writers to uphold, vis-à-vis the ACCME standards, are *ensuring content validity* and *ensuring that content is fair and balanced*.

Often medical writers work closely with faculty to develop CME content. A common approach is for faculty to send a set of slides that the writer then organizes, carefully fact-checks, and frequently develops further. Another approach is for medical writers to craft content that faculty then review. Either way, the medical writer must provide oversight to ensure the content is accurate and free from marketing messages or other commercial influence.

Regarding content validity, use of appropriate source material is key. Sources should include peer-reviewed clinical and scientific articles, published preferably in high impact factor journals. Published abstracts outlining

research to be presented at medical meetings are often peer reviewed and can serve as acceptable references. Posters based off these abstracts are generally not peer reviewed, but often present the most current information available and so may require a judgment call. Other valid resources include guidelines or special reports published by government sources or medical societies, or textbooks—although textbooks may not have the most current information. Many medical writers like UpToDate as comprehensive resource for clinical care, but it is not suitable as an original source.

Sources to avoid include blogs, Wikipedia, or other nonscholarly websites; other CE/CME programs; ineligible companies' websites or press releases; and of course, outdated or obsolete references.

Ensuring that content is fair and balanced means that, by ACCME's definition, information and recommendations or emphases in CE/CME "fairly represent" and are "based on a reasonable and valid interpretation" of information available on the topic.[5] The box provides a checklist to help medical writers to develop CE/CME content that is fair and balanced.

Ensuring CE/CME Content Is Fair and Balanced

- Use the best available source materials.
- Avoid focus on any one treatment.
- Give equal time to benefits and risks of treatment.
- Avoid brand names for agents, devices, or procedures; if it is necessary to use a brand name for one intervention, then provide brand names for all interventions.
- Be transparent about emerging therapies, including what clinical trial phase they are in.

CONCLUSION

There are many protections against bias in CME; prominent among them are the current ACCME Standards. On review of published studies, these protections would seem to be working, however, more rigorous and definitive research is warranted. In the meantime, medical writers can play an important role in oversight of CE/CME by ensuring that content they develop is fair, balanced, unbiased, and accurate, with a goal of promoting safe and effective patient care.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article. Statements and opinions presented in this article are the author's own and do not necessarily reflect those of current or past employers or contractors.*

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SCIENCE SERIES

Destigmatizing Eating Disorders with Medical Writing

Melinda D. Karth, MS, MA / PhD Candidate in Neuroscience, Purdue University, West Lafayette, IN

ABSTRACT

Eating disorders are a group of severe medical conditions that center around energy intake and sometimes body dissatisfaction. Despite their severity, eating disorders are often viewed negatively by both lay individuals and health professionals. This stigmatization is the result of inaccurate and exaggerated information about these illnesses. As health educators, medical writers are positioned to challenge and change these stigmas by creating and distributing accurate information about eating disorders. This article provides medical writers with foundational knowledge about eating disorders and background information on their stigmatization and offers suggestions for how to write about these conditions to reduce current stigmas and improve understanding of eating disorders.

EATING DISORDERS IN HEALTH COMMUNICATION

Health content creators construct health narratives by determining what information gets conveyed and omitted as well as the style and tone of that information. Medical writers, therefore, educate and influence people's attitudes toward medical conditions. These attitudes toward medical conditions can influence a variety of issues, including health research funding, health policy decisions and insurance coverage, support for individuals during medical treatment, and peer acceptance of individuals with certain medical conditions.

Despite the substantial responsibility health communicators have for creating accurate health narratives, online health information is often inaccurate and written by nonexperts.[1] This lack of credibility and accuracy in health content creation is concerning because the lay public and health professionals rely on and trust this information to educate themselves.[2,3] Misleading health information also influences how people think and feel about individuals with medical conditions.[4-6]

Information about eating disorders has been particularly inaccurate, omissive, and exaggerated in health communication, which has resulted in ongoing stigmatization of these illnesses.[4-6] Medical writers are well positioned to change this narrative by interpreting eating disorders research for nonexperts, yet information articles on eating disorders have largely been absent in medical communication. This absence may have contributed to the negative attitudes lay individuals and health professionals hold about these illnesses.[4-6] The pervasiveness of stigmas around eating disorders makes now a good time for medical writers to more deeply understand these medical conditions in order to reframe the narrative and reform attitudes toward them by creating informed, nonjudgmental, and accessible content.

EATING BEHAVIOR

Healthy Eating

Eating behavior exists on a spectrum, with healthy eating on the far left (Figure 1). The US government defines healthy eating as the daily consumption of a variety of nutritious foods and drinks with mindfulness for overeating or undereating.[7] Fulfilling your body's homeostatic needs is, therefore, one component of healthy eating. A second component of healthy eating involves a person's relationship with food.[8] Enjoying the foods you eat, avoiding food valuation (eg, labeling foods as forbidden), and having a flexible diet are additional aspects of healthy eating.

Figure 1. The eating behavior spectrum. Healthy eating is typically defined as fulfilling the body's homeostatic needs while maintaining a flexible diet. The transition from healthy eating to disordered eating is not clearly defined and can occur when a person's eating behavior does not fulfill their body's homeostatic needs (eg, restrictive or overeating); disordered eating also occurs when an individual experiences guilt or shame for eating. Eating disorders are extreme versions of disordered eating and are identifiable by diagnostic clinical criteria; eating disorders have a severe, lasting impact on the body and brain (eg, heart and gastrointestinal irregularities).

ISSN 2163-5315

Disordered Eating

To the right of healthy eating on the eating behavior spectrum is disordered eating. Healthy eating becomes disordered when a person engages in one or more of the following behaviors: restricting food, limiting specific foods, eating beyond satiation, experiencing guilt after eating, adhering to an inflexible diet, and/or experiencing nervousness when eating in public.[9] Under this definition, many accepted eating habits (eg, a low-carb diet) can be considered disordered eating. Disordered eating is not necessarily harmful but becomes a cause for concern when it impairs a person's physical health and life quality. Addressing disordered eating is important because if left untreated, it could progress into an eating disorder.[10]

Eating Disorders

Eating disorders are extreme versions of disordered eating and are diagnosable by clinical criteria.

Anorexia nervosa (AN): Individuals must restrict their daily energy intake in ways that interfere with their body's appropriate developmental trajectory.[11] Additionally, individuals must have an intense fear of weight gain, disturbed body perception, and denial of the severity of their low weight.

Bulimia nervosa (BN): For at least once a week for 3 months, individuals must engage in recurrent binge eating episodes.[11] A food binge is defined as uncontrollably eating an atypically large amount of food during a short period of time. Body disturbance and compensatory behaviors to prevent weight gain (eg, vomiting) must also occur.

Binge eating disorder (BED): For at least once a week for 3 months, individuals must engage in recurrent binge eating episodes.[12] A binge is defined as uncontrollably eating an atypically large amount of food during a short period of time. Eating until uncomfortably full and distress about binge eating behavior might also be present.

Avoidant restrictive food intake disorder (ARFID): Lack of interest in food that results in nutritional and energy deficits.[13] No body image disturbance should be present, and restrictive eating cannot be attributed to a separate medical condition.

Pica: Persistent eating of nonedible substances (eg, soil, paper, or chalk) for at least 1 month. These items cannot be culturally supported.[14]

Orthorexia: Not officially recognized as an eating disorder by the American Psychiatric Association but acknowledged as an eating disorder by clinicians and the public.[15] Involves an obsession with healthy eating that impairs an individual's well-being.

Subclinical: Individuals who do not meet all necessary criteria to be diagnosed with an eating disorder yet demonstrate extreme levels of disordered eating have a subclinical eating disorder. Subclinical eating disorders can be damaging to a person's health and well-being, despite not being officially recognized by the American Psychiatric Association.

The point prevalence for eating disorders in men and women across eating disorder subtypes has been estimated at 8.8% for adults and 5.7% for adolescents, with women having a higher lifetime prevalence compared with men (8.4% verses 2.2%).[16] In children (ie, ages 9 and 10), the lifetime prevalence for eating disorders across eating disorder subtypes has been estimated at 10%.[17] Historically, there is the misconception that eating disorders predominantly occur in White, heterosexual, cisgender individuals.[18] However, emerging research shows that Native American/Alaska Native women and Black women are as likely as White women to meet criteria for an eating disorder across subtypes, with these populations more likely to develop BED than White women. Similarly, LGBTQIA+ populations are at elevated risk for developing eating disorders and often have higher rates of eating disorder behaviors across subtypes compared with cisgender and/or heterosexual individuals.[19] These estimates across populations, however, could be low and inaccurate, as eating disorders go largely undetected by medical professionals for people of all ages and groups.[16,17] One reason for the underdiagnosis of eating disorders across populations could be the normalization of disordered eating in diet culture.

EATING BEHAVIOR COMMUNICATION

Diet Culture and Weight Loss

Definitions of eating behavior can be fluid and vague and, therefore, are often inconsistent within health communication. An example of this fluidity is diet culture.[20] Within diet culture, certain values are attached to different foods and lifestyle practices (eg, celery is a good food). These beliefs about food values and lifestyle practices are then accepted and ritualistically followed by people to achieve thinness, which is equated with health, morality, and increased social status in diet culture.[20]

Because diet culture limits what a person can eat and fixates on weight loss, its practices can be considered disordered eating. Dieting, however, is rarely considered disordered eating and has become normalized as a type of

healthy eating through diet culture communication.[20] Normalizing disordered eating minimizes the seriousness of eating disorders—it also influences how people think and feel about food, how they eat, and how they relate to their bodies.[20]

Eating Disorder Stigmas

The normalization of eating disorder behavior (eg, food restriction) in diet culture has contributed to stigmatization about eating disorders.[21] The most prevalent stigmas about eating disorders include personal responsibility for illness (eg, people with eating disorders are vain), attention-seeking (eg, people with eating disorders are not truly sick), and weakness (eg, people with binge-type eating disorders are too lazy and/or weak to lose weight through diet and exercise).[22] Consequently, people with eating disorders are often blamed for their illness and might internalize this self-blame.[4-6,23] Internalizing this self-blame might lower self-esteem, hope, and empowerment during treatment for people with eating disorders, which could prolong illness and decrease quality of life.[24] For example, women diagnosed with AN who feel stigmatized for their eating disorder (ie, personal responsibility) have a longer duration of illness, lower self-esteem, and more severe eating disorder symptoms compared with women who feel less stigmatized for their eating disorder.[20] Stigmatization about eating disorders can also foster negative reactions toward these illnesses in medical spheres, leading to the underdiagnosis of eating disorders.[6,23]

USING NEUROSCIENCE TO CHALLENGE EATING DISORDER STIGMAS

Destigmatizing Eating Disorders with Neuroscience

Eating disorders have a weak presence in medical communication, despite these illnesses involving and impacting nearly every organ in the body.[25] One reason for the weak presence of eating disorders in medical communication could be that these disorders are not considered to be serious medical conditions.[21-24] Unlike other illnesses, few pharmaceuticals have been effective in reducing symptoms; instead, treatments have centered around psychotherapy and behavioral therapy.[26] Emphasis on therapy in eating disorders treatment might be perpetuating the belief that these illnesses are solely psychological in nature. The omission of eating disorders from medical communication, however, needs to change, because medical communicators have a responsibility to accurately inform the public and health professionals about the complexities of medical conditions.

Writing about the brain's role in eating disorder signs and symptoms is one way medical communicators could reduce eating disorder stigmas within the public sphere and among health professionals. Research has demonstrated that people judge arguments supported by neuroscience information as more alluring and of higher quality than arguments supported by information from other sciences (eg, social science).[27] For example, when asked to judge the quality of several scientific arguments, university students rated arguments supported with neuroscience information (eg, brain image) as superior to the same arguments without neuroscience information. Research also shows that enhancing discussions about eating disorders with biological information, rather than strictly sociocultural information, improves people's attitudes toward these illnesses.[28,29] Consequently, including neuroscience information in communication about eating disorders could improve understandings of these illnesses and potentially reduce their stigmatization.

The Brain's Role in Eating Disorder Signs and Symptoms

Acknowledging the brain's role in eating disorder signs and symptoms (eg, restrictive eating) in medical communication could help destigmatize these illnesses by deemphasizing personal responsibility for eating disorder behavior. For example, research shows that atypically high levels of brain serotonin could contribute to AN signs and symptoms (eg, restrictive eating, anxiety, and cognitive inflexibility), whereas atypically low levels of brain serotonin could explain BN and BED signs and symptoms (eg, compulsivity, impulsivity, and binge eating).[30] Based on this evidence, selective serotonin reuptake inhibitors have been used with limited effectiveness in eating disorder treatments to rebalance serotonin and reduce symptoms associated with eating disorders (eg, depression).[26] Whether serotonin imbalances are present before eating disorder onset (eg, the result of genetic variants) or if serotonin imbalances emerge in response to disordered eating behavior (eg, starvation or excessive carbohydrate intake), however, is unclear.

Acknowledging how the brain constructs body image during an active eating disorder might also explain signs and symptoms of these illnesses. Body image is a complex concept describing how we perceive and feel about our bodies. This construct, which we create using our perceptions of and our feelings toward our bodies, influences the third-person image of ourselves we keep for self-reference in our long-term memory.[31] Consequently, our internal body construct might not accurately represent how we appear to others. Nonetheless, our brains work to make this construct as accurate as possible by updating it daily with current sensory information (eg, seeing our reflection). These daily updates to our body construct explain how our mental self-representations change as our weight fluctuates. The brains of people with AN, however, might not update

the body construct following weight changes because of disruptions in short-term memory processing.[31] These neurological disruptions to body construct updates in people with AN could explain why severely underweight people with AN insist that they are overweight. Potential causes for these processing disruptions include, but are not limited to, stress and social influence (eg, media images of idealized body types).[32] It is unclear, though, whether disruptions in body construct processing are present before AN onset or if they emerge in response to AN illness. Additionally, people with AN have reduced communication (ie, connectivity) between brain regions responsible for estimating body size and shape (eg, extrastriate and fusiform body areas).[33] As a result, these individuals assess their body dimensions erroneously. Body image therapy has shown to increase communication between these brain regions, resulting in more accurate estimates of body dimensions in people diagnosed with AN.[34]

Dysfunctions in gut-brain interactions might also contribute to eating disorder signs and symptoms.[35-37] The gut communicates information to the brain that influences not only what we eat but also our behavior and how we feel. Disorders of gut-brain interactions (DGBIs) (eg, dyspepsia) are common among people with ARFID, possibly because gastrointestinal discomfort contributes to food avoidance.[35] In these cases, an eating disorder likely develops in response to a DGBI, and treating the DGBI could reduce eating disorder signs and symptoms. Dysbiosis also plays a role in eating disorder signs and symptoms. In AN, certain bacteria imbalances in the gut microbiome could contribute to the reduced appetite, depression, anxiety, and challenges with weight gain associated with this illness.[36,37] For example, previous research shows that germ-free mice that receive fecal microbes from women with AN have reduced food intake, difficulties gaining weight, and increased anxiety-like and compulsive behavior compared with control mice.[38] How dysbiosis in AN contributes to these outcomes, however, is unclear. Increased gut permeability during an active eating disorder might also alter the immune system in ways that contribute to eating disorder pathology (eg, cytokines decreasing appetite).[37] It is unclear, though, if atypical gut composition and/or permeability develops prior to and/or during an active eating disorder.

DISCUSSION

The absence of eating disorders coverage in medical writing has potentially contributed to ongoing misinformation about and stigmatization of these conditions in public and health professional contexts.[4-6] Reducing these stigmas and improving eating disorders education in medical settings is important because the eating disorder recovery process requires a team of health professionals (eg, physicians, dieticians, and psychologists). Professionals working on an eating disorder treatment team, however, often lack specialized knowledge in eating disorders, which can slow communication between team members and interfere with treatment decisions.[39,40] Medical writers, therefore, could play an integral role in facilitating communication within eating disorder treatment teams by providing clear and accurate educational information about eating disorders. Effective communication among treatment team members is crucial for a patient's recovery; the longer an eating disorder persists, the more treatment-resistant it becomes, and the more it damages the brain and body (eg, heart and gastrointestinal conditions).

Educational content about eating disorders for health professionals could also help prevent these illnesses.[41,42] Physicians often overlook warning signs of an eating disorder, particularly in children and athletes, because of miseducation about these disorders and/or not taking these illnesses seriously.[43,44] Acknowledging signs of an eating disorder in children is important because eating disorders increase injury susceptibility and impact growth, brain development, and immune response. Physicians, therefore, need a more comprehensive understanding of eating disorders and disordered eating, specifically early warning signs (eg, lanugo body hair growth), common medical complications with eating disorders (eg, slow heart rate), biochemical markers of eating disorders (eg, low potassium levels), how to safely stabilize a patient with a chronic eating disorder, and how to define eating disorder recovery.

Finally, medical writers can help destigmatize eating disorders in the public sphere by interpreting emerging research about these illnesses for lay audiences. Important topics to write about include the underlying biology of eating disorders, emerging treatments, population-specific eating disorders (eg, different genders and ages), health consequences of eating disorders, obscure eating disorders (eg, ARFID), and recognizing subclinical eating disorder behavior (eg, inflexible eating). A challenge for medical writers communicating information about eating disorders to a nonexpert audience will be to acknowledge the limitations of the available information while maintaining credibility and authority. To accomplish these tasks, it will be essential for medical writers to dispel previous misconceptions about eating disorders and embrace the complexities of the evolving science.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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CREATIVE WRITING

Resonant Melodies of Healing: A Juneteenth Symphony in Medicine

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In the hallowed halls of healing's grace,
Where life and hope entwine, their embrace,
I stand as a black man, a vessel strong,
A symphony of compassion, an ode to belong.

In medicine's tapestry, a brush I wield,
With empathy's hues, a masterpiece revealed,
Each patient's story, a canvas divine,
Where healing strokes merge, transcending time.

With hands that bear both ancient scars and grace,
I touch weary souls, their burden I embrace,
The pulse of their pain, the whispers they hold,
I listen, I heal, with a love so bold.

Oh, Juneteenth, your resonant chimes,
Awaken echoes of bygone times,
When shackles clung tight, hearts bled in despair,
Yet hope birthed anew in the realm of care.

I close my eyes, visions spring to life,
Ancestors' strength beneath sun's golden strife,
In cotton fields' torment, they found might,
Their spirits ablaze, stars shining so bright.

Through anguish, they danced with resilience untamed,
A symphony of voices, freedom proclaimed,
From depths of their souls, liberation did flow,
Unyielding, unwavering, like rivers that grow.

Today, their spirits reside deep within me,
Their legacy guides, a beacon to see,
With every breath, their dreams I embrace,
A torchbearer for justice, in life's vibrant race.

Oh Juneteenth, I hear your triumphant song,
A chorus of history, echoing strong,
A day to honor, celebrate, reflect,
On journeys endured, lives intersect.

In medicine's embrace, we stand united,
With healing hands and hearts ignited,
Healers, dreamers, beacons of light,
Navigating shadows, dispelling the night.

For in this poem's tapestry, emotions cascade,
Let freedom's essence forever pervade,
May the world pause, listen, enraptured, and stirred,
By Juneteenth's echoes, hearts forever interred.

So let this poem transcend the earthly realm,
A lyrical gem, in brilliance overwhelm,
A testament to resilience, love's vibrant hue,
Where healing and Juneteenth intertwine, anew.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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ISSN 2163-5315

FREELANCE FOCUS


Brian Bass


Cathryn D. Evans


Alex Howson

Q1: How do continuing medical education/continuing education (CME/CE) medical writers balance the need for accurate scientific representation with the pressure to create content that aligns with pharmaceutical industry interests?

You'd think there was no need to even ask this question. But you'd be wrong. I once worked on a CME/CE project in which a supporter complained that faculty didn't give sufficient attention to the supporter's therapy in a live preconference education session. Subsequently, the education provider asked me to include additional material about the supporters' product in the downloadable slide deck "to keep the supporter happy." This behavior flouts a fair and balanced approach to content, threatens content integrity, and damages the regulatory firewall.

Accredited CME/CE content must be independent of any third-party influence or commercial interest. Standards and mechanisms have evolved in the United States to regulate the planning and delivery of CME/CE content and establish a firewall between commercial interests and education content. These standards and mechanisms are different in other parts of the world. In the United States, the Accreditation Council for Continuing Medical Education's (ACCME) 2020 Standards for Integrity and Independence in Accredited Continuing Medical Education specify the types of organization that can provide education, the types of content that they can create, and the criteria for creation. At a minimum, accredited CME/CE content must be evidence-based and adopt a fair and balanced approach to describing and evaluating relevant therapeutic interventions within a recognized standard of care for a given condition or disease. To this end, ACCME requires that education sponsors (often, but not exclusively, pharmaceutical manufacturers) have no role in determining content, editing, or providing materials to support the content.

Medical writers are instrumental in developing content for the purpose of educating health professionals on how to provide care for and treat patients. As such, we are *de facto* bricks in the regulatory firewall. It's our job to ensure that content meets the requirements of accreditation, so we need to be meticulous in the sources we review and use to create that content. We also need to be aware of the mechanisms in place to protect content integrity and prevent commercial influence. These mechanisms include financial and conflict of interest disclosures as well as independent and thorough content review processes. For the most part, these mechanisms are sufficient to maintain the firewall.

However, writers need to be aware that when pharmaceutical manufacturers issue requests for proposals to design and deliver education programs or activities, they have internal objectives that they expect such education to meet. The business and sales managers within education provider organizations know this. Their role in securing funding via the grant development process involves a delicate dance to ensure that content remains firmly within the 2020 ACCME Standards framework, yet also implicitly appeals to supporter interests. At times, they might zealously communicate these interests to writers. This is a form of tacit pressure. Similarly, when needs assessments are narrowly focused on a specific therapy compared with objectively identifying clinical and professional practice gaps, content is already skewed toward sponsor interests. Writing extensively about clinical trial data for one particular therapy is a common way that content gets skewed.

As writers, we are bricks in the firewall between industry and education, charged with maintaining content independence and integrity. We can do this by raising our awareness of areas in which tacit pressure can creep into the content development process and by pushing back on any potential to breach the firewall.

—Alex Howson

It is not unusual for a pharma/biotech client to try to "spin the data" in a Continuing Medical Education (CME) or other educational article so that a favorable light shines on their own drugs or therapeutic agents. The Accreditation Council for Continuing Medical Education (ACCME) has published guidelines/rules for CME material to qualify for accreditation and, presumably, most CME providers do try to adhere to these guidelines. You can access these guidelines easily

ISSN 2163-5315

via Google search. Nonetheless, some companies and/or their agencies will try to slither in a little bias toward a company product—this is not very difficult if the writer/author is clever.

Whether you are involved in *accredited* CME, Continuing Education (CE) for pharmacists, nurses, or *nonaccredited* educational material sponsored by a pharma/biotech company, the ethics remain the same, even if specific "rules" have not been published. Members of AMWA, as professional medical writers, are ethically obligated to pay attention to guidelines about content, sources, references, authorship, contributions, and acknowledgements.

How to balance the needs vis à vis pressure from clients? First, we must speak freely and openly with clients to let them know when the ethical lines are starting to be crossed. Second, if we are going to be asked to spin toward the positive—or even hide data, perish the thought—it is essential that we address this in fair balance with other similar and likely competitive therapies by including appropriate information about the other products as well.

If you do not have the moral integrity, or the professional confidence, to speak openly with your client about such things, probably you should not be a medical writer in pharma/biotech. These messages can be delivered quite diplomatically, no need for friction or hard feelings. We simply explain the rules, regulations, and guidelines around ethics in medical communication. Please note: if your client refuses to adhere to ethical standards and insists on the spin, I suggest you tacitly drop that client. (But, just in case of a future lawsuit,always make sure your recommendations are in writing, either in an email or within a manuscript—without in any way accusing the client, of course.) I have had to do this numerous times; it is not easy, but I do it. So should you.

—Cathryn D. Evans

* * *

Q2: When working on manuscripts involving multiple authors, how can medical writers help manage authorship disputes and ensure fair credit allocation following ethical guidelines?

It is not within the purview of a freelance medical writer to determine authorship or mediate their disputes—at least it should not be. If clients are passing this responsibility on to you, they are essentially asking you to be more than a medical writer; they want you to be the Project Manager, a function that pays more than medical writing, so be sure to raise your rate if a client asks this of you.

Yes, I have had to take this role at different times. Generally, I am crystal clear in my communication with coauthors (and clients) about guidelines and regulations; likewise, I am usually well aware of the politics within companies and academia, so I address the issue directly. The politics are out of our hands—this is up to the client and/or the chief author, investigator, or scientist. We cannot take responsibility for the politics.

—Cathryn D. Evans

* * *

Q3: How can medical communicators navigate cultural and linguistic differences in a global health care context, ensuring their work is accurate and culturally sensitive?

Medical communicators must always consider their audiences when developing content, but there's more to it than simply writing in one style for regulators, in another style for health care professionals, and in another style for lay audiences. There are differences in the way people learn and in the way people understand that go beyond reading and education levels. For example, although it may have been thought at one time that visuals are the best way to communicate to people with low reading skills, infographics have become a popular way to communicate the results of clinical trials to health care professionals.

The ability to access and utilize information is influenced by so many factors: race, ethnicity, age, culture, religion, sex, gender identity, sexual orientation, socioeconomic status, geography, physical ability, and neurobiology among them. With so many possibilities, is it surprising we're all different? That may be the biggest thing we have in common!

Although medical communicators should have always thought about at least some of this, diversity, equity, and inclusion (DEI) finally being at the forefront makes it a lot easier. Now our companies and clients are thinking about it, too. I think they're also more receptive to our doing something about it. It was wonderful when the American Medical Association *(AMA) Manual of Style, 11th Edition*, gave us permission to use "they" as a singular pronoun. The circles we used to have to write around a sentence in order to de-gender it!

One of the best ways I can think of for medical communicators to navigate cultural and linguistic differences in the global health care universe is to think about DEI constantly and allow it to drive questions up front about how a particular communication piece will be delivered, to whom it is intended, and what considerations can and should be made to optimize its value to this audience. This should be an actual topic of conversation at the beginning of any project—an agenda item! Establishing these guardrails from the beginning will help us develop content that is best suited to achieve its communication objective. I also think it is important for us

to consider the characteristics we give to patients when writing hypothetical case studies and patient journeys.

—Brian Bass

Much medical writing already occurs in a global context, requiring cultural awareness to ensure content resonates across different health care settings. Writers must consider linguistic, cultural, and identity differences to create inclusive materials that engage diverse audiences. We need to bring this same awareness to cultural and linguistic differences in a US health care context. If you're a writer in CME/CE, you are already likely doing so via the concept of cultural competence.

Almost 20 years ago, the Commonwealth Fund defined cultural competence as "the ability of providers and organizations to effectively deliver health care services that meet the social, cultural, and linguistic needs of patients." To this end, accreditation bodies such as ACCME, the American Nurses Credentialing Center, and the Accreditation Council for Pharmacy Education expect CME/CE providers to integrate cultural competence into education for the intended learner audience, be they physicians, pharmacists, or nurse practitioners. The California Medical Association, which accredits CME organizations in California, has also developed standards to ensure the inclusion of cultural and linguistic competency statements in accredited CME, as well as content that addresses, implicitly or explicitly, topics like communication skills, health care disparities, biases/stereotyping, cross-cultural pharmacological issues, and sociocultural factors that affect health beliefs and behaviors. ACCME is also working to ensure that DEI is incorporated into all aspects of accredited education.

A primary way to integrate cultural competence standards to CME/CE is by broadening representation within education content, such as in patient cases. We can diversify the social, cultural, and linguistic characteristics of patient cases by using diverse names, describing different marital statuses and relationships, and including images that represent people with disabilities, as well as Black, Indigenous, and additional people of color, and people in lesbian, gay, bisexual, transgender, queer, intersex, asexual, and many other identities (LGBTQIA+) communities. We can also educate ourselves on cultural norms related to communication, decision-making, family dynamics, spirituality, and other factors affecting health and health care.

Many tools and resources are available to help us navigate cultural and linguistic differences in both the United States and the global health care context, and to integrate cultural competence standards into CME/CE.

The Association of American Medical Colleges Diversity and Inclusion Toolkit is a terrific place to start, with resources on how to think about power and privilege, cross-cultural communication, and the diversity of identities in health care contexts. The Disabled and Here collection, Photoability, Tonl, the Gender Spectrum collection, and many other archives provide access to inclusive images. Resources such as the Inclusive Language Playbook: Writing for LGBTQ+ Communities,the 11th edition of the *AMA Manual of Style*, and the Council of Science Editors' perspective on inclusive sex/gender language can help writers avoid discriminatory or stigmatizing language.

—Alex Howson

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1. DeTora LM, Lane T, Sykes A, DiBiasi F, Toroser D, Citrome L. Good Publication Practice (GPP) guidelines for company-sponsored biomedical research: 2022 update. *Ann Intern Med.* 2023;176(3):eL220490. doi:10.7326/M22-1460

Online Resources for Freelance Writers

ACCME Standards for Integrity and Independence in Accredited Continuing Medical Education: https://accme.org/publications/standards-for-integrity-and-independence-accredited-continuing-education-pdf

ACCME Accreditation Criteria: https://www.accme.org/accreditation-rules/accreditation-criteria

International Committee of Medical Journal Editors: Defining the Roles of Authors and Contributors: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Association of American Medical Colleges: Diversity and Inclusion Toolkit: https://www.aamc.org/professional-development/affinity-groups/cfas/diversity-inclusion-toolkit/resources

Inclusive Language Playbook: Writing for LGBTQ+ Communities: https://communicatehealth.com/wp-content/uploads/ch-lgbtq-playbook.pdf

Council of Science Editors: Inclusive Language Communication: https://www.councilscienceeditors.org/inclusive-language-communication

Inclusive Imagery:
https://www.awesomefoundation.org/en/projects/114332-disabled-and-here
https://tonl.co/
http://photoability.net/
https://genderspectrum.vice.com/

AMWA JOURNAL V38 N4 / 2023

TOPICAL FEATURE

PART 2 IN A 3-PART SERIES

The Business of Medical Writing: Communication, Leadership, and Corporate Responsibility

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ABSTRACT

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business. A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association National Conference to discuss this topic. The topics of value proposition and business models; communication, leadership, and corporate responsibility; and financial acumen will be reprised in this 3-part series. The series will also include thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these concepts earlier in the medical writing career path. This Part 2 manuscript focuses on communication, leadership, and corporate responsibility.

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business: the value proposition, the finances that drive strategy and decision-making, the financial goals, and effective communication.

A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association (AMWA) National Conference to discuss this theme.[1]

The topics of value proposition and business models,[2] communication, leadership, and corporate responsibility, and financial acumen will be reprised in this 3-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path. This Part 2 manuscript focuses on communication, leadership, and corporate responsibility.

The authors' collective experience comprises the following medical writing work environments:

- Freelance business
- Small business/vendor
- Department leadership of small- to mid-size biotech company and large-sized pharmaceutical company

The moderator's (Joan Affleck - JA) prompt is provided for each topic, followed by each perspective on the topic. In some cases, text from the session has been paraphrased for optimal clarity in this medium.

COMMUNICATION IN A BUSINESS CONTEXT

JA: ***There's so much to being a business leader. We've talked about value proposition, business models, finances;[2] another area I want to touch on is communication. Now—communication: this is our stock-in-trade, right? We should get this part. But I'm willing to bet you have all discovered that communication is a little bit different in the business context, and I wonder what kinds of communication situations you've run into and how you've used communication to help your business succeed. Maybe you've had to speak differently with potential or actual customers, employees, and collaborators, maybe even a detractor. So, how do you see communication as being an essential element of business leadership or business acumen?***

DD: It will make or break you, regardless of where you sit. That's the bedrock of what we do, and people ask you all the time as a medical writer—"So, *what* is it that you do?" If you can explain that to them clearly and communicate what you're doing, that's half the battle because you've explained what the baseline is in terms of this conversation you're having. Within teams it's the same requirement: you need to explain to the team what it is you bring to the table, why you're doing it, and what they need to know. The important thing for me and for my teams is to answer the questions before my teams ask them of the writer or the writing team—to anticipate things, to have a contingency plan in place, and to be able to communicate that to put the client (and that is the team, in my case) at ease with the sense that the writer and the writing team have been here before and can see what's coming before I can see it. If we can do that,

ISSN 2163-5315

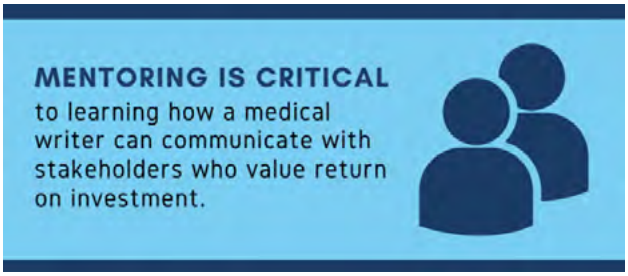
it takes away a lot of the tension within the team that really doesn't need to be there. And it comes with experience, I agree, but you can communicate to the team, "This is the first time doing this kind of project; we need to learn a few things from you, but I'd like to help you with what we bring. We know how to write the document, but we have to work together." And that's OK, too, but as long as that's explained up front, people understand where everybody's coming from. Again, it's this same transparency of communication that carries the weight of the work forward in a good way.

JA: ***That "taking away the pain" that Jeanette talked about earlier.***[2]

DD: Right, as much as possible. The writers are the document development experts, and they know many things about the regulations and all the trappings around what has to take place with the document. The team members have to focus on their expertise, or the client has to focus on whatever this product is that you're contributing to; we have to help them not worry about our piece of it to the degree we can, and that's important.

JA: ***As some of you have mentioned earlier—everyone learns to write; therefore, they think they are the writer, so we may need to get them to stay in their swim lane!***

JT: I think communication is so important, too, in just being able to explain to your clients what you think the gains are going to be. The best example of this I had was when I was working in-house in a department and was in a meeting with a senior regulatory person and the president of the company, who was a typical MBA—very focused on the return on investment and [having] very bold goals for her company. They were talking about narratives and how those are done, and I made the mistake of saying, "This is the industry-standard way of doing this," and I found out later that this was a phrase that tended to make her head explode! But it took that other senior leader in regulatory leading me down the path in this meeting to say, "OK, well, I understand that, but which parts of this process can we break down—which parts do we need to stay married to, to maintain the quality, and which parts can we potentially try to be a little more bold about?" I immediately saw where she was going with it, too;…I understood that what I had said was maybe not the right thing to say. Having someone who you can observe and who can model that behavior to help you translate what you are trying to say from a medical writing standpoint into something that makes sense to someone who is interested in that return on investment is critical. Again, that's where that mentoring comes back in; and it



doesn't even have to be someone within a medical writing group, it could be a senior leader in regulatory or some other adjacent function who can help navigate and model some behaviors.

BB: From a freelancer's standpoint, I think there are 3 key communication areas that freelancers need to pay most attention to, and if they do, it will really help with their success (and by that, I mean delivering their value to their clients) (Figure 1). The first is responsiveness. The only thing worse than when a client reaches out to you with a new project and they don't hear from you, is when you are in the middle of a project and the client reaches out to you and gets crickets. Nothing will instill apprehension faster than that. We're all busy and know how hard that is, but one of the things I've worked very hard at is responding almost immediately to clients, even if it's just to say, "Hey, I got your message; I'm in the middle of something, and I'll get back to you later"—just so they know I'm here and on top of things. The second thing is confidence when I'm speaking with clients—trying to speak the language of the project and the work that needs to be done so my client knows that I get it, that I understand what we are all talking about. This gives them the confidence to move past "Can they do the job?" and get into "Let's get them the information they need to get the job done." The third thing is frankness. Where the other 2 things are probably mostly of benefit to the client, this third thing is really of benefit to the freelancer. People who are on staff don't think about certain business aspects the way freelancers do, and I find myself having to explain in very lay terms why things work differently for freelancers than they do for staff people. As a quick example, I estimate projects and invoice on a project basis rather than an hourly basis. A lot of clients don't get this. I find it helps clients to understand me better when I explain to them that if a project is ultimately, let's say, $1,000 for the sake of argument, does it really matter if it takes me 10 hours or 2 hours to get to the end result, or 20 hours? It shouldn't, because the bottom line is, can it get done within the budget, and is it done properly? The better we get at what we do, [we] also get faster at it. Because there is a limit to what anyone will pay on an hourly basis for someone, it forces us to work more the better we get in order to earn the same money we made when we were less experienced. When I lay it out in those terms to clients,

you can see a little lightbulb go on that they understand the dynamics involved, and I find that helps build the relationship.

JA: ***Is that the same for you, Jeanette, in your business?***

JT: Slightly different. I think historically—and I totally agree with everything Brian just said to a large extent—we do tend to go in the time and materials direction for the main reason that when you have an expanded network, you would really have to have a lot of capital behind you to be able to absorb the type of risk you would need to. Say the project gets delayed and you can't bill for a unit until 3 months from now—well, you still have to pay your people. It really depends on the individual circumstances and what type of business model makes sense. But [as] we've also been considering lately, does that make sense for some of our clients but not all of them? I think you have to have the acumen to know when to reexamine your model, and it should be done frequently to make sure that it still makes sense and is optimizing the amount of time you put into what the dollar amount actually ends up being in the business. A kind of dual approach is needed there—and the ability to be self-reflective about it.

JA: ***And look at that: you've brought in the finance with communication and business model all in one example, and you added in that really interesting factor of being able to assess risk in business. Fascinating! We have described this panel discussion in the brochure for the conference as being for midcareer writers. But afterward, I realized we don't really know when we should be talking about and teaching writers business skills. What are your thoughts about that: is midcareer the right time, or do you have a different idea?***

BB: I vote for teaching it from the very beginning.

DD: Day 1—agreed.

BB: When we're learning how to write, we should be learning economics and finance—and teaching it.

JT: I completely agree. From the freelancer perspective, one of the things I've intentionally done recently is talking about the sales funnel in our operations group (Figure 2). Again, for us, that's people coming in earlier in their career and learning the operational aspects; they may or may not aspire to be medical writers, [but] they need to understand where those touch points are with the clients, and why those things are important to that concept of operational excellence, which is our pitch. Because if they don't, we're not able to achieve that operational excellence. They also need to understand what keeps the client coming back in the sales funnel, which is the ultimate goal; you don't want to court a client once and then have them leave you—that wouldn't be time well invested. So, helping people who are coming into the department understand where they fit into it—not only once but continually—is a return on investment for [my taking] the time to talk about that.

Figure 1. Three key areas for communication for medical writers.

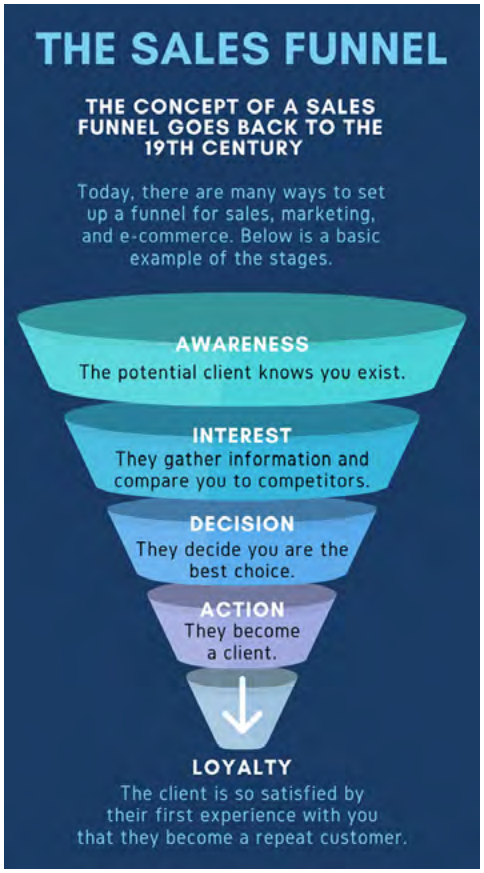


Figure 2. The sales funnel. *Adapted from: Crail C, Bottorff C. Sales funnel template and examples for 2023. Forbes Advisor, July 3, 2023.*[3]

DD: In particular—more so for the freelancer than for the in-house employee—each of us has to know what our value is in terms of what we bring to the client. And if we don't know how much we can bill, or how much we are worth, or what it is we think we can demand for what it is we are asked to do, then the whole idea of business dissolves. If you're providing something and expecting to be paid for it, by definition you're in business, like it or not; and you have to understand that if you're offering someone a product and expecting them to give you money, then all of the trappings of that understanding have to go hand-in-hand—you can't have the work product and the money be separate and not think about or not understand [the relationship of] one to the other.

JA: ***I think that, too, even in a corporate situation in which you might feel a little bit more removed, there's benefit in owning your project more, owning those cycle times, owning the quality rating of your project—to take pride in that and work toward higher standards.***

BB: Freelancers need to understand where they are in the food chain. It really comes back to this value proposition[2]; in order for everyone to be able to make money and justify costs, there has to be that "wow factor" at the end that makes everyone say, "That was really a great experience—let's do that again."

JA: ***Love it! [Because] none of us benefited from a formal program to teach us about the business aspects of medical writing, let's do a little futuristic thinking, a little pie in the sky: if you could help design a program, what would that include? What are some examples of the best ways for writers and editors and leaders in medical writing and medical communication to actually acquire business literacy—what do you think we need to put in place?***

BB: From a financial standpoint, I would recommend courses in bookkeeping, estimating, budgeting.... Whether you are a freelancer or someone who is ultimately going to run a department, you need to know all those things.

DD: You have to be an expert project manager. You have to understand time and materials and how much you can accomplish in a unit of time. [That emphasizes] the importance of the right metrics calculated and maintained routinely [to] give you data from which you can better cost your projects. To Brian's point on the project basis, if he didn't know what he could do in a unit of time, he would never be able to come up with a project estimate that was of any value; you have to understand what you can do. We have to teach the writer to understand themselves at the beginning, [to] know what they can do and say, "OK, I can write 1,000 words in 2 hours," and that means I can write a manuscript every 3 days [or whatever that happens to be], and therefore I can do 2 manuscripts per week. [Only] then you can begin to see how all these pieces add up, and that's the important part—to make the connection between the academic work we know as writing and the numeric concepts we associate with business. But the 2 things have to go together; they can't be separate.

JT: One component I might add to that—and this might surprise you—[is] emotional intelligence. One of the hinging points of my career was [when] someone handed me [Daniel Goleman's] book *Emotional Intelligence*,[4] and we read it as a group in the department. Again, this was in the context of a regulatory department, so there were lots of benefits in terms of being able to use that material if you were presenting to the [US Food and Drug Administration], but you could also use it to leverage conversations with your colleagues in other departments and bring them to a point of alignment on certain issues.... Studies have actually shown that [although] for certain skills you can't teach an old dog new tricks, emotional intelligence is not one of them; it's one you can continue working on no matter how advanced you are in your career. So, [this applies] not only for those just coming in, but also continually throughout your career, as well as in leadership [positions].

LEADERSHIP

JA: ***Another thing that I think you all have touched on at one point or another is this idea of mentoring and observing and having access to leaders that you can just observe and learn what tricks they have up their sleeves to make the business work. Do any of you have an example from your own experience of how your understanding of business has helped you lead a team through a period of significant change? We all know change is the only constant, and I'm just wondering how it has served you.***

BB: For me, an area that's a good example is negotiating. Part of my goal—and maybe that's why my particular freelance model seems to work pretty well for me—is for all the freelancers on my team to make as much money as possible and make the client say, "Wow, that was fantastic—let's do that again!" Therein lies the value for all of us. But we all come to the table with various skills, and some of them are strong, and some of them are not. One of the areas I find myself working with the freelancers on my team on is when the client pushes back on an estimate. The one thing I think I've taught to everyone on my team is to be really open and

honest in our conversations with the client about where they think things went off, so we can go back and look at the way we prepared the estimate to see where we may have gone wrong. As much experience as we all have, we're not always perfect, and to have the opportunity to have clients feel open enough that they can come back and discuss money with you, which is something no one is comfortable talking about, is really great for me. Because 9.5 out of 10 times, we end up coming to an agreement that works for everyone.

JT: Obviously, one challenge that everyone had is COVID. Within our business, when it first began, we saw a lot of early-phase stuff fall off the map if it wasn't in a critical area, so one thing that I think really preserved our business model at that point was the fact that we had diversified the types of things we work on. So, we work on a little bit of late-phase stuff, a little early-phase stuff, a little in rare disease, a little in oncology; and so, because we took that approach intentionally and are looking all the time at how healthy our clients are—what are they bringing in in terms of overall income, and do we need to pursue any new business—we were able to quickly balance our portfolio once certain things started falling off at that point.

DD: I guess things are a little bit different in-house, but from a negotiation standpoint and an emotional intelligence standpoint, [there is] absolutely the same obligation on the part of the writer to really know how to speak with the team, anticipate things, and really instill trust and confidence. COVID changed our work environment, as it did for almost everyone, and we all ended up working remotely, which is different than the in-house team members were accustomed to by and large. As a manager, you have to be resilient and [amplify] that resiliency to your staff and get them to remain motivated in the right ways; and oftentimes that comes down to a lot of interpersonal interactions—even more so from a 1:1 perspective than you may do otherwise in normal business because we were all under these unusual pressures we had never faced before. Making an open acknowledgment that we are all in this new world together was important for everyone to understand and say, "Look, whatever this is, we'll get through it one way or another, but we have to keep our eye on the work and give us some focus and a sense of purpose at the same time." I think that really carried a lot of people forward in the right way.... At the end of the day, we are still people.

CORPORATE RESPONSIBILITY

JA: ***I want to pull a little bit on this thread of corporate responsibility.[2] How does that fit into your role as business leaders? For example, Dom, I know that where you work, the company has a big investment in corporate responsibility, to the point where they give drugs away for free sometimes. Do you see that play out in your department?***

DD: Yes, because at least from the leadership standpoint, many of my colleagues are committed to medical writing, and they understand what the field is about. And that's really a unique component, in that having that breadth of knowledge about what medical writing is and what it takes to do it allows us to focus on the people in our teams and try as we can to develop them to their fullest potential. We have a responsibility to the people on the one hand, but the responsibility to society at large comes through at the end of the day when we bring the products through and market those drugs based on the filings we support. So, looking at all of these integrated pieces really allows us to contribute to that, and being at Merck has allowed us to be part of that.

JA: ***Others—comments on that piece about corporate responsibility?***

JT: I always like to say profit and progress are not mutually exclusive. So, in continuing our business, making sure it is profitable, and doing all of the things a responsible business owner can do, I think there are opportunities for the team to get involved in things they care about. As an example, this summer we ran an internship for the first time, [which both] afforded us the potential to expand the available resource pool to medical writing in general [and offered] something that wasn't really out there for this particular group of individuals. It was really a pilot for us, so we... are going to keep working on that [using our first intern's feedback]; everyone who was involved with that process was really energized by it, too, and that's something that is easy to forget sometimes. But it's something we really play close to the heart here because we have a particular viewpoint as a disability-owned business in terms of some of the challenges we have faced over time in industry, and we want to use that experience to make the pathways positive for anyone who does want to enter the field from any walk of life.

JA: ***Music to my ears! We have an internship program and an apprenticeship program in my department.***

BB: My company is not large enough to have an internship program, so I do a lot of mentoring. It's important to me to do that as a way of giving back to the industry I'm in and giving back to the world that I work in and live in, to help bring people up to that level of experience and expertise that make them someone I could bring onto my team. But unlike my colleague's groups in which you have a certain amount of work to do and need to bring people in to do it, my company doesn't have to grow to bring in people to do work; I'd rather not take work that we're not qualified and do not have the best people to do, so I'm in a position to be able to flex that in the opposite direction.

JA: ***I think we do a little bit of both, right Dom?***

DD: At times, yes. We try to provide balance for our people, and we try to move the work around in a way that's manageable for all involved. It doesn't always work out the way we'd like it to, but again, nothing is perfect.

JA: ***In terms of taking on new work, though, we are similar in philosophy, Brian, in that we don't just take on work for the sake of taking on work. We take on work for which we feel we are qualified and to which we feel we will really bring added value.***

BB: That really is the bottom line. The worst circumstance anyone could find themselves in professionally is to realize down the line they should have said no.

JT: Yeah, absolutely, and I would say the converse is also true. Some of the best experiences I've had professionally have been when I was afraid to say yes. I was offered a promotion, and I had a 9-month-old. Well, that was a tough one, but I said yes, and I was better in the long run for it as hard as it was. But weighing those options is important no matter what you decide.

BB: And that is how we stretch ourselves—you're exactly right, Jeanette. If we don't say yes to things that we're not positive we can do, then we never learn how to do them. We never prove to ourselves we can do them. I guess it's being sensitive to where that magical line is.

DD: But knowing who to ask if you have questions along the way also helps, right Brian?

BB: Oh yes, indeed, Dom—absolutely. Yes—someone you can turn to, to get that leg up when you need it.

LOOKING TOWARD THE FUTURE

In Part 1 of this 3-part series, the authors discussed how this panel was an initial dialogue meant to "kick off a broader discussion of the many aspects of business leadership as it applies to our work as medical communicators."[1] The authors concluded that having a comprehensive business curriculum, namely a pathway whereby medical writers can readily learn the skills needed to demonstrate leadership while also participating in decision-making activities earlier in their careers, would benefit the writer toward the goal of developing a strategic mindset while learning fundamental business topics.[2]

One of the key functions of leaders is to execute on a business's strategic plan, which outlines corporate goals that are intended to "trickle down" to departments and individuals.[5] Well-stated goals might even ensure the goal is in a specific, measurable, achievable, relevant, and time-based (SMART) format—but, typically, a strategic plan only tells you *what* the goal is (eg, file New Drug Application [NDA] for Drug XYZ in Q1 of 2023") and occasionally the metric it will be measured by (eg, authorization of XYZ in the US by start of Q2 2023). The plans most often do not cover the how or the why of arriving at that particular outcome. If you are a leader focusing intensely on doing your best to meet the company's goals, you could still be missing a very important part of the equation. Here is an example: as a leader, you looked at the above corporate goal for filing the Drug XYZ NDA, and you did your diligence and determined you need to hire a new vendor to be able to complete the work. You did not realize that procurement has been given a directive to increase diversity and inclusion by trying to onboard small and diverse vendors, so your vendor selection and qualification process became delayed and could now comprise a risk to the submission deadline. This background discussion was not part of the corporate goal but became critical toward understanding how the company wanted the goal met and wanted business to be done to optimize corporate responsibility.

After all, learning to communicate about business—and, most importantly, how to listen to what is important to business leaders—is currently not a distinct component of medical writing education.[6-8] As previously discussed,[2] the AMWA Recommended Training Outline for Regulatory Writers[6] acknowledges that the skills in the outline are only some of the skills and proficiencies needed for professional success but does not distinguish business knowledge as a separate training topic, although it does note that "soft skills are crucial for working efficiently, gaining trust, communicating and collaborating effectively with colleagues, and achieving personal and company goals." The outline also

highlights leading without authority, influencing and persuading, and negotiation, which are some of the skills medical writing leaders need to acquire, but applying these skills in the day-to-day with teams on documents and applying them to a management audience are different endeavors. Exactly how these skills can be acquired and understood as early as possible in medical writers' careers remains our fundamental challenge.

At the end of the day, whether we are the CEO of a medical writing group within a corporation, of our own corporation, or of our own freelance business, we all work for a company, and a company must have a way of doing, or an ethos, that guides its daily work. It is the responsibility of leadership to build a bridge and ensure not only that a company's goals are met but also that its ethos is incorporated into everyday work in an authentic way to make certain that the outcomes will be positive and sustained over the long term. This means that medical writers in leadership (or pondering leading) should strive to understand the importance of corporate responsibility and actively seek to connect their personal ethos with that of the company, as well as to communicate that outward to their medical writing teams and customers.

Author declaration and disclosures: *J. Affleck and D. De Bellis are employed by Merck & Co, Inc, and are shareholders. B. Bass and J. Towles note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N4 / 2023

TOPICAL FEATURE

The Key to Better Regulatory Writing: Tell Your Device's Story

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ABSTRACT

Medical device development requires regulatory documentation, but what constitutes good writing in those documents has no well-established pedagogy. Senior regulatory experts often use the language of storytelling when asked what makes for good regulatory writing. Twelve such senior experts interviewed for this article responded with some version of, "It all depends on how you tell your device's story." But what does this claim really mean? Regulatory documents are long and technical; they are not usually considered in literary terms. This article explains how storytelling can help hone your regulatory writing. It uses the literary components of setting, plot, and character to show how selecting contextual details, tightening causal connections, and keeping the focus improve document quality. Furthermore, it employs real life examples taken from the FDA and notified body submissions to illustrate exactly where and how those details, connections, and focuses contribute to good storytelling. Key transitional phrases, syntactical constructions, and relevant contextual data make all the difference.

Successful medical device development involves truckloads of documentation, from design control records to clinical literature to post-market surveillance. Yet none of these documents are accompanied by as much handwringing as the device's regulatory submissions. Years and years of work hang suspended by the thread of a single submission packet. Will the FDA approve it? Will it be CE marked?

Curiously, little training is associated with the specific writing skills that such vital regulatory documentation demands. The early twentieth-century boom in engineering birthed an entire profession of technical writers. Medical writers can attend specialized graduate programs at a number of universities. Yet outside a smattering of individualized courses or certificate programs, the regulatory field has no commensurate area of professionalized *writing* expertise, even though degrees in medical device regulation abound.

Is document quality inconsequential to regulatory agencies? In 2014, *Medical Writing* devoted 2 different issues to argue the contrary.[1,2] More recently, survey results published by the *AMWA Journal* in 2021 demonstrate the value of good regulatory writing: 87% of the regulatory reviewers surveyed claimed that poor writing impedes their assessment.[3]

This lack of a distinct professionally adjacent writing field may be due to the strict stipulations regulatory agencies provide. Major medical device manufacturers have company templates for what to write. Technical understanding of the product and its relationship to the clinical field and current state of the art is likely more important than the quality of a submission's prose. Yet the AMWA's 2021 survey demurs. Moreover, when you talk to longtime regulatory insiders who have worked for the FDA or notified bodies, they tend to stress the writing. In my experience, when you ask these experts what makes for successful regulatory submissions, they answer with some version of, "It all depends on how you tell your device's story."

Regulatory experts frequently stress the importance of storytelling, which I soon realized as I collaborated with them. (A benefit of working at a clinical research organization is the exposure you get—not only to multiple devices but high levels of expertise.) The first time I heard it was from a senior colleague who had worked at the FDA for decades. I was helping to draft part of a pre-submission letter to the FDA. "Remember," I was counseled, "it's all about the story we're telling." A few days later, it popped up from another ex-FDA employee in a similar circumstance.

Then, in the middle of a large meeting, I heard a consultant who used to work with a notified body insist, "We must help our clients to tell their device's story well—that is crucial!" Medical device regulation is a highly technical field—it demands familiarity with the precise terminologies used in medicine, engineering, and law. Why were these technically proficient industry insiders talking about stories?

It struck me as strange. Story is, after all, a catchall type of term. It's amorphous, applying as much to a novel as a painting, as much to an advertisement as a lie. Storytelling belongs in the dusty corners of coffee shops, not brightly lit biomedical engineering labs. Yet it was near ubiquitous advice: tell your device's story, they said, over and over again.

ISSN 2163-5315

Many universities offer courses in "medical humanities," a field that harnesses the power of narrative to explore how humans experience medicine. Story is essential for how that field understands medical practice and can overlap with the concerns of technical communicators.[4] Yet these regulatory experts didn't mean anything close to the medical humanities. They meant story as an organizing principle, not an encounter with the humanities.

I began interviewing 12 senior regulatory experts to understand what they meant by storytelling, asking them pointed questions to draw it out as exactly as possible. What follows in this article uses their terminology's literary sensibility, only amplified with particulars extrapolated from their generalities. Setting, plot, and character encompass the practices necessary for good medical device storytelling.

ESTABLISH THE CONTEXT: SETTING

You'll often hear novelists say they long to provide a distinct sense of place. Near the beginning of her essay "Place in Fiction," Eudora Welty claims that a novel's sense of place determines its quality.[5] Beyond a lofty goal, however, she notes that fiction is structurally "all bound up in the local." Place, or the setting of a story, is crucial to how it works. The setting gives a story its feel, its sense of completion. Setting makes a story *believable*.

Good storytelling means providing the appropriate amount of context. This was usually the first thing a person said when I asked them how to tell a device's story: "Provide enough context—but not too much!" Too many details overwhelm; strive for the right ones. Although the reviewers who read regulatory submissions often have impressive technical backgrounds, they will likely know little about your device. They won't know how your device was developed or how it fits into a specific medical field. Prejudices from previous experiences might incline them to make unhelpful assumptions about your device. It's your job to preempt such misunderstandings. Your ability to put the device in the appropriate setting makes your submission believable.

A couple of practices can help make this happen. First, do not make the mistake of assuming executive summaries and conclusions are unimportant textual padding. Make use of these sections. If you're using boilerplate language instead of crafting these key passages to convey the appropriate context, you've thrown away a vital chance to communicate with your reviewer.

Second, pay attention to phrasing. Adding helpful contextual details to frame your claims and data will create the right setting. Below is a paragraph taken from a pre-submission letter to the FDA (altered, with data and references removed). It is meant to provide an example of how attention to phrasing establishes helpful context. The underlined phrases below provide background to situate the data in the device manufacturer's deliberately selected setting. In brief, the goal was to clarify how an off-label procedure (in the US) was safe and had clinical data, although from elsewhere.

> Other US surgeons are employing off-label procedures to address the need for a more unified approach to heavily calcified disease extending into the aorta. In a special issue for *Endovascular Now*, the New York-based vascular surgeon John Smith explains his preference for "advanced treatment of lengthy aortic disease with a covered endovascular reconstruction of the aortic bifurcation (CERAB) technique for complex aortic disease." Dr Smith's preference is rooted in data now familiar to vascular surgeons. Published studies comparing standard endovascular treatment, CERAB, and open surgery found higher 30-day mortality rates, but better medium-term patency with open surgery compared to the endovascular techniques [*hard data here.*] Due to its recent development, long-term data is not yet available for CERAB techniques.

Note how the writer contextualizes the opening sentence with what came before—we can infer that the previous paragraph discussed the views of US surgeons. Beginning with "Other US surgeons" establishes the critical context for the paragraph: we're still talking about the US and its surgeons. That's what's often called a "signal term." The surgeon quoted in the second sentence is placed in a US city. Does the city in which this doctor practices matter? Not really. But US practices and the US population matter for the FDA, and we want to remind the readers that this comes from US-based surgeons' opinions. This provides a meaningful context to interpret the safety and performance data that closes the paragraph.

Finally, note the last underlined phrase. "Due to its recent development" puts the finishing touch on the setting. Setting is about place; yes, certainly. It's also about time. We want to know *when* something took place. The timing matters, too. The data are put into a chronological history of medical developments. Taken together, these small additions create an interpretive framework for the reviewer.

KEEP THE THREAD: PLOT

The British novelist E. M. Forster once said, "'The king died and then the queen died' is a story. 'The king died and then the queen died of grief' is a plot."[6] Plot, in Forster's famous formulation, provides the causal relationship between events in a story. The king's death and the queen's death are simple events. We can tell the story of when, where, and how they happened. But for that story to have a plot

we must answer *why*. The king's death causes the queen's death—she died "of grief." See how the event now takes on a causal relationship? Something made her death happen: the queen died *of grief*. That's what we want in a plot—we want clear causal connections.

Regulatory documentation keeps its plot thread by drawing out causal connections. Almost everyone I interviewed emphasized keeping a sense of connection at various levels: between claims and data, between arguments, and between sections. This even applies to long documents, such as the Clinical Evaluation Reports required as part of marketing submission to the European Union.

If explicit connections are missing and the reviewer struggles to follow your case, you've opened the door to doubt. An auditor or reviewer could give up in frustration and write you off as unprepared. Or they might begin to wonder—how does this relate to such and such? Soon they will start to wonder what you're not saying. Are you overlooking something or—worse—hiding something? A lack of clear causal connections can erode your authority and invite counterarguments that might never have arisen with tight transitions between points.

One straightforward way to think of this is, don't skip the rationales! Robust rationales are critical to communicating the logic behind design changes to the concerned regulatory agency. The basic principle of providing robust rationales—explaining *why* something changed instead of simply glossing over *how* it changed—can be broadly applied to all the claims you make in your documentation.

Other strategies can help you keep your causal connections clear. First, signal the beginning, middle, and end with signal terms such as first, second; after, before; etc. This provides a sense of order. Second, use transition words that make the causal relationship between sentences clear. Keep the plot going with words like another, yet, while, furthermore, etc. Third, remind the reader of the overall arc of the document and how this particular point relates to the overall point. For example, the State of the Art section in a Clinical Evaluation Report, which often feels forced and out of place, should be linked back to the rest of the document. That section places your device in the context of relevant treatments. Do so!

Fourth, we were all taught to use topic sentences, but how consciously do we do so when using a template for regulatory documents? Yet those topic sentences provide the logical connections between your main points. They provide roadmaps to what is coming and how that point connects to what came before. Topic sentences keep the reader engaged—on the writer's terms.

Additionally, the logical connections in your prose should go even deeper than topic sentences and transition terms. The way each sentence links up with the following sentence is a simple way to keep your logical connections tight. Think in terms of the grammatical logic of subjects and predicates. Usually, the predicate presents the information that needs to be communicated about the sentence's subject. If you consider your sentences as proceeding from a familiar subject to a new predicate, your prose will keep its logical connections rooted in its grammar.

The example below is from a clinical literature review on a device used during high-risk percutaneous interventions. This short paragraph explains how the indication of high risk has a unique history that matters for understanding how the device in question works. Although this paragraph does not reference the device, it connects each sentence to the following through the logic of its grammar. The paragraph opens with a historical claim and ends with a justification for the increased vulnerability of the relevant population. As you read through it, note how the subject in bold font links back to the underlined predicate preceding it.

> **Percutaneous coronary interventions (PCIs)** now carry less risk than they did nearly half a century ago, when the procedure was first introduced. All PCI patients who were considered **"high risk" (HR) patients** early in the procedure's development. Back then, **procedural success** was <60% and a cardiothoracic surgeon was required to be in the operating room. **Procedural success is now nearly 100%** and the definition of HR-PCI has now focused on a specific subset population. Specifically, **patients who are HR-PCI typically present** with unprotected left main coronary artery, multivessel, and bifurcation lesions, as well as those with chronic total occlusions. **Such conditions** are indeed "high risk."

English usually begins sentences with the subject of the sentence and then introduces some new information about that subject in the predicate, the second part of the sentence, which is often a verb or verb phrase. Regulatory documents should be written in what is called Plain English (or sometimes, Global English), whether they're for a notified body or the FDA. Plain English is simplified and strives to be nonidiomatic. Thinking about the basic subject-predicate structure of your sentences can help produce the clarity associated with this style. More to the point, it will help you keep the plot by tightening your writing's causal connections.

MAINTAIN FOCUS: CHARACTER

Another way to tell your story well is to develop key characters. Who's at the center of your story? How will you keep the reader's focus on that main character? In the data dump of technical specifications and clinical findings, it can be easy

to lose focus. The true protagonist in every regulatory document is the patient. Remember, each piece of data you pull into your writing represents an actual human being. Real people hide behind your statistics. The point behind developing new medical devices is, after all, to help people! The reviewers at regulatory agencies are there because they want to help people—both by keeping them safe and enabling new developments. Don't become careless in your tone or terminology such that your writing loses that human focus.

Other types of character inhabit regulatory documents. The device in question may be your focus, but related alternative treatments are key to how readers perceive its value. Take the following review of the current state of the art for stenting. Example #3 below is taken from the State of the Art section of a Clinical Evaluation Report on a guidewire device. Stenting, not any specific stent, is the character being developed here. As you read through it, note that we are told *why* stents are employed over other procedures and *why* new stents have developed over time. A meaningful pattern has been presented here: a pattern that creates the story of stenting. Note how the information is being interpreted for us so that we keep the focus on the stenting.

Finally, notice how the underlined text explains the value of the nearby claim (in bold text). Sometimes the claim in bold text comes first, as in the first sentence, and sometimes it follows the explanation. But the sentences are built to focus on stenting while developing and enlarging what that entails.

> Stenting: Today, two main types of bare-metal stents are available: self-expanding stents and balloon-expandable stents. **Because of the technical limitations of self-expanding stents, and their tendency to provoke greater neointimal hyperplasia**, balloon-expandable stents are now used for nearly all coronary stent procedures. Covered stents are most frequently used to treat emergent coronary perforations. **As restenosis is a significant problem with bare-metal stents**, drug-eluting stents were designed with immunosuppressant or cytotoxic drugs to inhibit neointimal hyperplasia. **The risk of very late events associated with the implantation of permanent metallic stents (eg, stent thrombosis and restenosis, fracture)** led to the development of fully bioresorbable stents, more commonly known as bioresorbable scaffolds.

This is only an example, one way of thinking about how to keep your focus. Nevertheless, it demonstrates the value of explaining your claims and how this simple rhetorical practice helps clarify the paragraph's focus. Paying attention to sentence construction, as this writer has done, gives the reader a clear sense of how stenting has developed.

CONCLUSION

The goal of this article has been to distill insights gleaned from a group of experienced regulatory experts on why they value good storytelling so highly. Although they often used literary terminology, it was unclear what that meant for them in practice. However, if you establish the context or setting for the device, keep the causal connections clear, and maintain focus on key characters, you'll be off to a good start.

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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TOPICAL FEATURE

Value of Medical Writing—Using the Regulator's Perspective (2021 Survey Results) to Educate and Empower Medical Writers

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ABSTRACT

In 2021, an American Medical Writers Association (AMWA) working group conducted a survey to gain an understanding of how regulatory agencies perceive the value of medical writing. The survey showed that document quality is extremely important to the timely and efficient review of an application and identified key factors affecting document quality that negatively impact application approval. In response to this, a working group ran a series of roundtables at the AMWA and European Medical Writers Association conferences to gather opinions from medical writers about this survey and how we can best communicate these ideas to authoring teams. This article discusses the feedback obtained in those roundtable sessions and presents the working group's proposal for a set of resources to empower medical writers to implement change.

INTRODUCTION

Medical writers bring value across the health sciences, driving efficient approaches for the delivery of high-quality medical communication documents targeted at diverse audiences including regulators, payors, physicians, and patients.[1–3] The results of the American Medical Writers Association (AMWA) 2021 regulators survey[3] demonstrated that regulatory reviewers recognize the value of medical writers in the preparation of regulatory documents submitted to obtain new drug approvals worldwide. Of the regulators surveyed, 70% agreed or strongly agreed that medical writers improve the quality of documents, and 87% agreed or strongly agreed that sponsor companies with established medical writing functions and rigorous document development processes and standards produce higher quality submissions. Importantly, 87% confirmed that poor document quality impedes regulatory assessment, and 77% of the regulatory reviewers agreed or strongly agreed that poor document quality delays the approval process.

Thus, the impact of poorly written documents can be substantial. The survey showed that poor document quality negatively affects the applicant's goals, which in most cases would be the approval of a drug or expansion of indication. When the regulators were asked which one document quality issue they encounter most frequently, the 3 top answers were excessive length/repetition/verbosity, poor explanation of rationale, and nonadherence to guidance. These are all things that medical writers can have a direct impact on if their authoring teams agree to using common ideas considered to be good medical writing practice (eg, lean writing and effective review processes).

The current working group was formed to educate medical writers about the importance of these regulator-conveyed issues with document quality and to empower writers by proposing evidence-based resources they can use to advise and convince their authoring teams about what good medical writing practice is and why it is essential for successful regulatory documents.

EDUCATING AND EMPOWERING MEDICAL WRITERS

The survey revealed that regulatory reviewers appreciated and recognized the contributions and value of trained medical writers. The AMWA Value of Medical Writing workstream focusing on the regulator's perspective concluded that "Training must equip medical writers to lead teams that create documents that are concise and clearly present the messages supported by the data."[4] Moreover, recognizing the regulator's appreciation for the medical writer's contribution is a powerful tool to guide the industry toward more streamlined writing practices that will ultimately aid and streamline drug approvals. Making the writing community and their teams aware of this feedback should be a priority for the profession.

ISSN 2163-5315

To this end, the data from the AMWA Value of Medical Writing workstream were presented at roundtable sessions at the European Medical Writers Association conference in May 2022 and the AMWA conference in November 2022. The medical writers who participated in the roundtables were informally surveyed to assess what their opinions were about the survey results. We also sought their input on how they thought a set of resources would help to implement change in the specific areas of improvement identified and what they felt would be useful to include in such a set. The feedback from these sessions was formative for developing the concept of the set of resources to help implement change. The key ideas are summarized below.

First and foremost, it was recognized that the medical writing community needs to be made more aware of the 2021 article. Of approximately 20 medical writers who attended the roundtable sessions, only 2 had read the article and were aware of it prior to the session. This made it clear that there is a very low awareness of the article among medical writers. There was general consensus that, for people to actively use a set of resources based on the data from the article, they need to be well-versed in the upstream survey and results.

Beyond that, we asked for input on what participants felt a set of resources should be to aid in educating their teams. Based on the responses, it was understood that the resources should provide material to help medical writers understand and raise awareness about the following key topics:

- Having a clear, strategic presentation of rationale
- Streamlining the writing process
- Demonstrating value for management from using good medical writing practices

To help teams understand the need and methodology for a *clear, strategic presentation of rationale*, the set of resources should

- provide examples and arguments for explaining the rationale for study design and in-text data selection,
- present arguments for having the medical writer actively participate in kickoff and strategy meetings and lead comment resolution meetings, and
- describe and explain how professional reviewers review documents.

To help with *streamlining the writing process*, the set of resources should

- present arguments that a medical writer can share with their team to support the use of lean writing and demonstrate that it is not necessary to repeat all the data in text (eg, the regulators clearly expressed a preference for lean and concise writing; lean writing needs less quality control time),
- contain examples of what non-lean writing looks like compared with lean writing and include simple examples of how streamlining the language can be achieved, and
- provide a list of good writing practices based on the results.

To demonstrate *value for management*, the set of resources should provide arguments that can be used to convince management of the importance of well-written, lean documents. In addition, the participants of the roundtable sessions felt that the set of resources should be useable for training medical writers and include visual aids that can be embedded in other materials.

Ultimately, the goals of the set of resources are to raise awareness and highlight the importance of

- delivering succinct documents with clear and concise reporting of results and messaging,
- educating teams on how professional reviewers review documents, and
- empowering medical writers to act as strategists and key drivers of their documents.

The topics associated with these goals are outlined in Table 1 on the next page. Based on this, a set of resources will be created comprising a set of documents and slides that can be used with different audiences, depending on the setting and document types.

We hope that disseminating this set of resources will help spread the important message of the regulators survey and give medical writers effective arguments to show their teams that by applying good medical writing practice to reduce length/repetition/verbosity, increase clarity, and provide a better explanation of rationale, we can accelerate the drug approval process and deliver medicines to patients faster.

Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article. The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or AMWA.*

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Table 1. Goals and Topics of the Resources Set for Medical Writers

Goals of the Resources Set	Resources Set Topics
Delivering succinct documents with clear and concise reporting of results and messaging	Good writing practices How to avoid poor explanation of rationale and unclear key messaging Removing repetition: give examples Increasing the use of cross-referencing both within and between documents Using succinct bulleted lists or tables to convey key information, as appropriate, instead of long paragraphs Contemporary abbreviation rules (not defining at first use: explain how this saves time in multiple areas) Reducing excessive length The value of using a single template for study reports and other documents (for uniform structure and data presentation)
Educating teams on how professional reviewers review documents	If time is of the essence, what should the team focus on first to ensure the document will help them easily find the answers to the questions they have—what are the key messages, and have we made sure a reviewer sees these in each section? Help teams understand the importance of effective cross-referencing to guide reviewers to supporting information. Giving the assessors the messages in succinct text that aids them to prepare their assessment reports. If they do not have to slog through writing those reports from scratch and can copy over well-written text that has clear messages, it can save days of time in completing the assessment.
Empowering medical writers to act as strategists and key drivers of their documents	MW is present at kickoff and strategy meetings so they properly understand the rationale behind the messaging: only in this way can they effectively communicate the message. MW should lead the comment resolution meetings—they know best where the unanswered questions are in the document and where there are gaps that need filling. MW should be proactive in referring to relevant guidances, agency websites, and primary source references to tailor and suggest text within the dossier. Provide a strong argument for explaining the rationale for selection of the data. The MW should have a clear vision of how the data work together to build the overall story—and should advise the team on optimal ways of presenting these data (in figures, tables, text) to best communicate the flow of logic that leads to the conclusions. Clarification of roles on teams: no one person owns the content of a document; there is a team of authors who all contribute to a document. Yet, the medical writer owns the master version of the file and is responsible for making sure comments are all addressed and applied consistently throughout. There cannot be a free-for-all, or the MW will lose oversight of document integrity and what has been changed.

MW, medical writer.

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TOPICAL FEATURE

Results of the 2022 AMWA DEI Survey

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The AMWA Board of Directors (BOD) issued a statement in June 2020 acknowledging that health and well-being for all cannot exist alongside endemic racial health inequities. The statement emphasized that diversity is a strength that enriches AMWA membership. In 2021, the BOD confirmed the goal of creating a more inclusive, diverse, and collaborative environment for members and set a direction for enhancing diversity and inclusion efforts within the organization. In addition to the updated AMWA diversity, equity, and inclusion (DEI) statement,[1] the BOD appointed a Diversity and Inclusion (D&I) Assessment Task Force. The task force was charged with analyzing membership data and gathering member input to help determine the current status of the organization's D&I; identify deficiencies, needs, opportunities, and challenges related to D&I; and recommend initial strategies to enhance D&I within the organization.

The task force developed the 2022 AMWA DEI Survey with the goals of gaining a clearer understanding of the existing diversity of membership, identifying current shortcomings, and recognizing how to build upon AMWA's current strengths to enhance the overall atmosphere of D&I within AMWA. This survey allowed the task force to assess the demographics of our members. Asking the right questions and offering members the chance to holistically share information about their identities provides AMWA with the opportunity to better serve their members and learn key areas for improvement.

The survey was sent to 4,649 AMWA members, of whom 397 responded. The demographic data presented here identify some clear opportunities for growth, particularly as relates to better serving members who are disabled and members who may belong to marginalized groups. In March 2023, the task force reported to BOD with survey results and recommendations. The scope of this article is to summarize the information on AMWA membership gathered as results of the survey. Responses to open-ended questions and decisions to be made on the basis of the survey responses are not included in this article and will be addressed in future communications.

MEMBERSHIP STATUS

To ensure that the survey captured an accurate picture of current AMWA membership, respondents were asked to provide their membership status. Of survey respondents who answered this question (N = 396), 98% (n = 388), reported that they were current members of AMWA at the time of the survey.

AGE

We received 395 responses to the question about age. AMWA membership is primarily aged 40 to 59, with 28% of members identifying as aged 40 to 49 (n = 112) and 28% of members identifying as aged 50 to 59 (n = 109). Twenty percent of members were aged 60 to 69 (n = 78), 16% aged 30 to 39 (64), and 2% aged 25 to 29, with 4% either younger than 30 or over 80.

VETERAN/MILITARY STATUS

Of the 388 respondents to this question, 99% did not identify as a veteran or member of the US military service.

EDUCATIONAL BACKGROUND

One hundred eighty-five members (47%) hold a doctoral degree, whereas 34% of members (n = 133) hold a master's degree. Nineteen percent of members (n = 74) have attained an undergraduate degree.

EMPLOYMENT ROLE, AREA OF FOCUS, AND EXPERIENCE

To characterize the work roles of AMWA members, 54% (n = 215) identified themselves as employees of companies, whereas 37% (n = 148) are freelance workers. Five percent are looking to enter the field, and 4% do not actively work in the field or are retired. The largest group of members worked for pharmaceutical or biotechnology companies (22%, n = 86), with 20% working in medical communication as a close second. Eleven percent work for a research or academic institute, 9% work for a clinical or contract research organization, and 7% work for a medical research education

ISSN 2163-5315

company. Six percent of respondents work for a health care organization or provider, and 6% of respondents work for a nonprofit organization or professional society. Five percent of respondents work for a medical device company, and the remaining 3% work for a publisher or journal office (2%) or a government agency or contractor (1%). The remaining 11% of respondents (n = 42) work for a different type of organization or client.

AMWA respondents' primary work interests or focus areas were primarily regulatory writing and editing (32%; n = 127) and scientific publications (26%; n = 102). However, 10% of respondents (n = 39) listed their primary work interest/area of focus as health communication/public health/journalism/patient education. Fewer than 10% of respondents selected selected each of continuing education, publications for professional audiences, promotional writing/marketing/advertising/public relations, medical affairs, grant proposals, and sales training as their primary work interest or focus area, and 6% of respondents selected that their primary work interest or focus area is another type of medical writing or editing.

Survey respondents varied in experience, but 46% (n = 193) of respondents have worked in the field from 11 to 30 years, with 23% (n = 91) working in the field from 11 to 20 years and 23% (n = 92) working in the field from 21 to 30 years. However, the percentages that do not fall into this group are still sizable, with 17% (n = 68) who have worked in the field for 0 to 2 years, 14% (n = 54) for 3 to 5 years, and 13% (n = 52) for 6 to 10 years. Finally, 10% (n = 40) of respondents have worked in the field for more than 31 years (Figure 1).

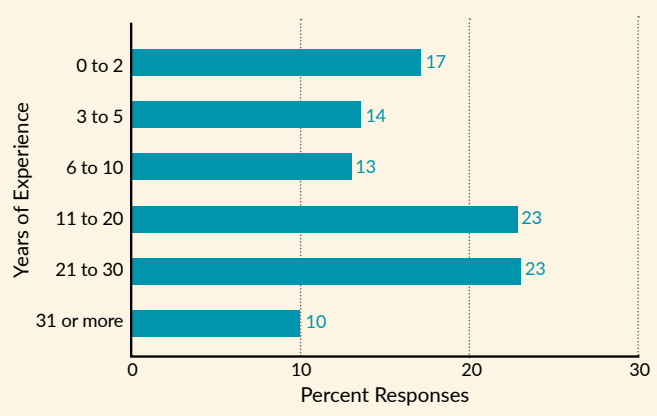

Figure 1. Question 14: Years of experience as a medical writer and/or editor. Total respondents = 397.

RESIDENCY

By far the largest group (91%; n = 360) of respondents who answered this question lived within the United States. The state with the highest number of respondents was Pennsylvania (9%; n = 33), with California and North Carolina also at 9% with 30 respondents each. Massachusetts and Texas each had 7% of respondents, or 24 respondents each. New Jersey, Illinois, and Maryland each had 5% (with 18, 17, and 16 respondents, respectively), and 4% of respondents lived in each of Colorado (n = 15), New York (n = 15), and Florida (n = 13). For respondents who lived outside the United States, the most common country of residence was Canada, with 50% (n = 17) of respondents. Remaining numbers of respondents are too low to disclose without potentially identifying members.

DISABILITY, CHRONIC ILLNESS, AND NEURODIVERSITY

Of 395 survey respondents, 17% indicated that they had a disability; the most common disabilities were chronic illness (43%), mental health condition (24%), and other (12%; details were provided on the survey but are not included to preserve the privacy and identities of the respondents) (Figure 2).

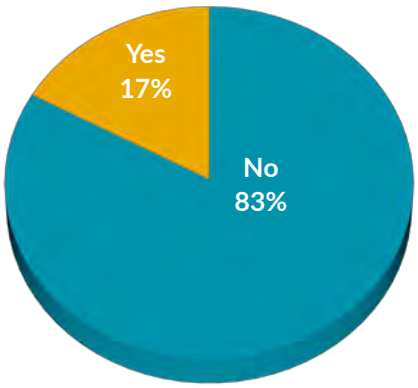

Figure 2. Question 7: Do you have a disability? Total respondents = 395.

Among 42 respondents who declared a disability and did not experience barriers to participation in AMWA, methods of accessing AMWA services included online (64%) ("internet," "computer," and "virtually"), other (14%), online or other electronic medium with in-person attendance (ie, hybrid) (12%), with help of accommodation or regulation within their own limits (7%), with help of assistive device (5%), and via mailing list (2%). Of note, given that some respondents who answered no to having a disability responded to this question (n = 11), there appear to be AMWA members interested in both online and hybrid formats in general and who would benefit from accessibility accommodations even though they may not consider themselves disabled. Several respondents mentioned in their response restrictions/barriers to access, including expense (n = 2) or other barrier (n = 1). Several (n = 5) respondents also indicated that although they attend virtually when they can, they wish that there were more virtual options for participation, celebrated the greater number of virtual options available in recent years, or noted limited options for virtual

participation. Twenty-three participants who answered that they had a disability did not answer the question on how they access AMWA services.

Among 17 respondents who declared a disability and noted that they require accessibility accommodations for virtual conferences, online learning, webinars, or virtual networking, accommodations included having available virtual/online learning opportunities in general (35%); technological options enabled for closed caption, chat, and/or ability to control speed of or repeat audio (29%); other (24%); and copies of large-font materials and advance availability of materials (6% each). Similar to the above, some respondents who answered no to having a disability responded to this question (n = 5), with an additional accommodation for diet-related concerns, so there appear to be AMWA members interested in having these types of accommodations available even though they do not consider themselves disabled. Multiple respondents noted a need for accommodations beyond technology and physical space (eg, scent-free spaces, noise reduction).

Among the 397 survey respondents, 5% indicated they were neurodivergent, with 13% indicating they were not sure if they are neurodivergent and no response for 3% (Figure 3).

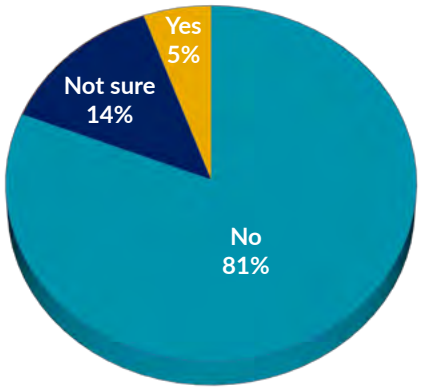

Figure 3. Question 9: Are you neurodivergent? Total respondents = 385.

Most of the respondents who scored AMWA as 1 or 2 with respect to Accessibility and Belonging were disabled. Among respondents who gave low (1 or 2 out of 5; the scale ranged from 0 [poor] to 5 [excellent]) scores to "Rate how well AMWA is currently doing on" belonging, diversity, equity, and inclusion, most respondents who rated AMWA's performance on "belonging" as 1 or 2 (n = 17) identified as having a disability, and half of respondents who rated AMWA's performance on "diversity," "equity," or "inclusion" as 1 or 2 (n = 29, 20, and 22, respectively) identified as having a disability.

RACE AND ETHNICITY

Over 80% of the survey respondents were White (n = 326), with 9% identifying as Asian American, Southeast Asian, East Asian, or of Asian descent. Members who identified as Black, African American, or of African descent were 5% of respondents, and 4% of respondents identified as multiracial or mixed race, with many identifying as 2 or more races. Six percent of respondents self-identified as Latine/Latina/Latino/Latinx or Hispanic. Additional remaining percentages were too low to disclose. It will be important in future analyses to evaluate associations between self-identified race and ethnicity and answers to survey questions regarding belonging, inclusion, accessibility, equity, and diversity.

SEXUAL ORIENTATION AND GENDER IDENTITY

We examined answers to the pronoun, gender identity, and sexual and romantic identity questions. Of 79 respondents to the question about the individual use of personal pronouns, 53 respondents indicated that they use "she/her," 52 indicated that they use "he/him," and 8 indicated that they use "they/them." Additionally, 15 of 79 respondents selected "I do not use personal pronouns." There were some challenges evaluating this section of the survey. Some LGBTQIA+ people do not identify with any personal pronouns. However, many of the respondents who selected this last option seem, based on their answers to other questions on the survey, to have done so either because they did not understand what personal pronouns are or because they were using the option to protest the inclusion of multiple gender identities.

When asked about sexual and/or romantic orientation, 19% (75 of 397 respondents) represented diverse sexual or romantic orientations and 82% (n = 324) identified as heterosexual or straight. See Table 1 for the sexual or romantic orientations included.

Table 1. Question 5. Sexual and/or romantic orientation or self-identify. Check all that apply.

Answer Choices	Responses (%)
Heterosexual	225 (58)
Straight	118 (31)
Bisexual	19 (5)
Queer	16 (4)
Lesbian	14 (4)
Gay	11 (3)
A sexual or romantic orientation not listed here. Please specify:	11 (3)
Demisexual	9 (2)
Asexual	5 (1)
Questioning	4 (1)
Demiromantic	3 (1)
Panromantic	3 (1)
Pansexual	3 (1)
Aromantic	1 (0)
Biromantic	0 (0)
Total Respondents	**385**

Regarding gender identity, 12% (n = 49) of respondents are transgender or gender diverse. All other respondents (88%; n = 348) identified as cisgender (or identifying with the sex they were assigned at birth).

Additional information provided in the open response questions indicates the following opportunities for AMWA: additional work needs to be done to (1) refine the language used in these questions, (2) address safety and inclusion for these members, and (3) provide platforms for educating members on inclusive language. Additional analyses of open response questions related to AMWA's culture of inclusion around sexual orientation and gender identity will be provided in a follow-up article.

DEI AND AMWA

Survey respondents were asked to rank 8 strategies they felt would be most helpful for AMWA as it works toward cultivating a more inclusive culture. The 3 top-ranked strategies were having diverse representation in AMWA authors, speakers, and presenters; having diverse representation in leadership/governance; and providing programs and resources on DEI topics. Respondents were also asked to identify topics for potential resources relating to DEI that would be most helpful to them as medical communicators. The top 3 responses were resources on using inclusive language in medical communication, how to develop inclusive health communications, and health equity and health disparities.

The task force is grateful to everyone who participated in the survey. We hope that this information will enable AMWA to learn how to enhance the overall atmosphere of D&I within AMWA.

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Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N4 / 2023

CONSCIOUS WRITING

Best Practices to Guide Decisions of Authorship and Author Order in a Research Manuscript

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ABSTRACT

Over the past 75 years, medical publications have included a growing number of authors. As a result, research teams face challenges in deciding who qualifies for authorship and in what order the authors should be listed. These challenges can lead to tension among research teams that is related to a large number of authors, a lack of knowledge about authorship guidelines, limited experience in research, power dynamics and work culture, and even unethical practices. To overcome these challenges, research teams may look to medical writers and editors for guidance. As a result, medical writers and editors need to be prepared to share best practices for deciding which authors qualify for authorship and which authors should be listed in the acknowledgments. Medical writers and editors also need to be aware of and advise against unethical authorship practices, including honorary authorship and ghost authorship. Medical writers and editors can also guide research teams in best practices for ordering authors, including understanding the meaning of author positions, determining author contributions, planning authorship from the start, establishing authorship responsibilities, agreeing on how to resolve disputes, keeping track of contributions, and documenting discussions about authorship. With this guidance, research teams can adopt best practices for ethically granting authorship and fairly ordering authors based on their contribution to the work.

Until the 1950s, publications were largely written by 1 author.[1] Since then, publications have included a growing number of authors, especially publications in medicine.[1,2] Between 1945 and 1988, medical publications gained 1.26 authors every 15 years (versus 0.41 authors in other branches of science).[2] And across the sciences, the greater number of authors on publications has paralleled the rise in international and interdisciplinary research collaborations.[3]

This rise in the number of authors has created 2 important challenges. First, research teams must decide who qualifies for authorship. And second, they must figure out the order in which to list the authors who contributed to the work. These challenges can occur in any research team, but they can be exacerbated among junior researchers who are not well versed in best practices for authorship or among teams that have unethical authorship practices.[4,5] To overcome these challenges, research teams may look to medical writers and editors—internal or external to the team—for guidance.

To help medical writers and editors guide research teams, they need to fully understand the guidelines for authorship. They also need to be prepared to share best practices to help research teams determine who qualifies for authorship and strategies to help them determine in what order authors should be listed.

WHO QUALIFIES FOR AUTHORSHIP?

To determine who qualifies for authorship, many journals provide guidance on their website. Most often, these journals recommend that research teams use the guidelines created by the International Committee of Medical Journal Editors (ICMJE).[6] According to the ICMJE, each author should fulfill all 4 of the following criteria.

1. The author made substantial contributions to conceiving or designing the work, or to acquiring, analyzing, or interpreting the data for the work; and
2. The author drafted the work or reviewing it critically for important intellectual content; and
3. The author reviewed and approved the final version of the manuscript to be published; and
4. The author agreed to be accountable for all aspects of the work, including being willing to answer questions about the accuracy or integrity of any part of the work.

To ensure that listed authors meet all these criteria, many journals ask research teams to include a description of what each author contributed to the work in the manuscript, which the journal often publishes with the manuscript.

But what if a contributor does not meet all 4 authorship criteria? These contributors should be acknowledged

ISSN 2163-5315

instead.[6-8] For example, contributors who supplied funding, research materials, lab management, administrative support, or writing and editing assistance may not meet all 4 criteria. These contributors should be thanked for their specific contribution (eg, provided funding, critically reviewed the manuscript, collected data) in the acknowledgments section.

Some research teams disregard this guidance and grant honorary authorship.[5,9] In other words, they give "gift authorship" out of respect or gratitude for someone (eg, supervisor, department head) or "guest authorship" to a well-known researcher to try to amplify the quality or prestige of the paper. In some cases, honorary authorship may also be related to "pressured authorship," in which a person of authority pressures more junior staff to include them as an author when they do not qualify.[9] Because these practices are unethical and can be considered research misconduct, medical writers and authors need to be prepared to advise against these practices.

Another type of authorship is ghost authorship. With this form of authorship, a contributor is not listed as an author, even if they made contributions worthy of authorship.[5,9] This practice occurs for a number of reasons, such as an author electing to exclude themselves or a research team hiring a professional writer. The ethical nature of ghost authorship is complex and should be discussed carefully among the research team and other contributors. For example, if a professional writer qualifies for authorship based on the ICMJE criteria, they should be included in the author list.[10]

IN WHAT ORDER SHOULD AUTHORS BE LISTED?

Once a research team determines who qualifies for authorship, they must figure out in what order to list the authors. This process can be challenging, partly because ordering conventions vary between fields, guidelines, and journals. And the ICMJE guidelines do not provide any guidance on how to determine author order.[6] Some journals offer guidance that can help research teams determine author order. But with professional guidance from medical writers and editors, and some easy strategies, research teams can agree on a fair order to list the authors.

The Emphasis on First and Last Authors

The 2 most coveted (ie, most valuable) positions in a publication are the first and last author positions. The first author is most often the person who has contributed the most to the work.[7,8,11] This contribution can involve designing the study, performing experiments, collecting data, analyzing data, writing the manuscript, or other tasks related to the project.

The last author is usually—but not always—the supervisor or principal investigator who oversaw the project.[12] In some fields, the person who oversaw the project may be listed as the first author. The person who oversaw the project often receives much of the credit when the project is successful, or the criticism when something goes wrong.

The Importance of Corresponding Author

The corresponding author is the person who takes primary responsibility for communicating with the journal. They ensure that all required information is submitted to the journal, and they receive all updates related to the submission, such as the status, reviewers' comments, and final decision.[6] The corresponding author is often the person who oversaw the project, so most research teams will designate the last or first author as the corresponding author.[13]

The Relative Contribution of In-Between Authors

Between the first and last author positions, authors are usually listed according to their relative contribution to the work, from the most to the least.[7,8] To determine this order, many research teams use a mathematical approach. They will choose which items will appear in the manuscript, determine how much each author contributed to those items, and then rank the items based on their importance to the manuscript. Then, they will calculate each author's total contribution to the manuscript and order the authors from the most to least contribution.

The Challenges of Equal Contribution

In some cases, research teams believe (or calculate) that more than 1 author contributed an equal amount to the work. And this equal contribution can apply to any position in the author order, including the first and last positions. Some journals will let research teams indicate whether authors contributed equally to the work. But even then, the team has the (sometimes daunting) task of choosing the order of the authors who contributed equally.

This task can be even more challenging when the equal contribution applies to the coveted positions of first or last author.[14] For example, the first "first" author will get more visibility than the other "first" author because the first "first" author is the first—and sometimes only—name a reader will see. This same challenge can occur with the last author position, because the last "last" author often gets the most credit for the work.

What can you do to settle a debate about equal contribution? A simple approach is to just list them alphabetically, although the use of this approach has declined over time.[15] Some research teams will order authors who contributed equally by their seniority in the group, the degree of difficulty needed to carry out a specific part of a project, or a combination of these approaches. And other teams get creative. For example, a researcher at Stanford University

had 2 researchers in his laboratory play 3 games, and the winner was given the first slot.[16] This approach is certainly not conventional, but it added a fun spin to an otherwise daunting task.

HOW CAN TEAMS PREVENT AUTHORSHIP CONFLICT?

Discussions of authorship and author order can lead to conflict among research teams. And this conflict is influenced by a variety of factors, including power dynamics, experience in research, and the culture in the institution, department, or laboratory.[4,5] To navigate these conflicts, medical writers can guide research teams to use the following best practices.

Plan Authorship from the Start

The best way to mitigate any issues in granting authorship and ordering authors is to plan authorship from the beginning of the project, before the writing or even the research project starts.[7,8] During an initial meeting with the research team (or an established committee for larger studies),[17] discuss the ICMJE guidelines and define what is considered a contribution that qualifies for authorship in the context of the project. This approach ensures that all potential authors know the expectations—and potential consequences of not meeting them—from the start.

Establish Authorship Responsibilities

In planning authorship, discuss and clearly define the roles and responsibilities of each author (ie, who will do what), with the caveat that these contributions may change as the project evolves. These discussions could be facilitated by creating a modifiable authorship grid that clearly outlines the responsibilities and contributions of each potential author.[18] This grid could be informed by standard taxonomies of author contributions.[19,20]

Agree on How to Resolve Disputes

Before a potential dispute occurs, discuss how the team will resolve disputes that may arise. This discussion will ensure that the team has an objective approach to manage a dispute. For example, the team could agree to resolve disputes with a neutral third-party, such as an administrator or researcher far removed from the work.[12] Or the team could get creative, as the Stanford researcher did, by having 2 authors play a game to determine the author order.[16]

Keep Track of Contributions

As the project and writing progress, keep track of everyone who contributed to the work and how they contributed. Then, at regular intervals or major milestones, discuss authorship and whether your team might need to make adjustments to ensure all contributors qualify for authorship based on the ICMJE guidelines. If the team is using an authorship grid[18] or other tracking method, be sure to update the tracker with each discussion.

Document Discussions About Authorship

To ensure a smooth authorship process, summarize all discussions in an email or document so they can be tracked. Ask all potential authors to review this document and agree, in writing, with the described details. This approach will ensure all authors stay aware of their contribution to the project. Then, when submitting the manuscript, declare the authorship contributions (and even clarify the order of authors)[12] in the manuscript where appropriate.

CONCLUSIONS

Authorship can be a source of tension among research teams. This tension may be related to the rise in the number of authors, knowledge of authorship guidelines, experience in research, power dynamics and work culture, and even unethical practices among teams. With guidance from medical writers and editors who are well versed in authorship best practices, research teams can adopt procedures for ethically granting authorship and fairly ordering authors based on their contribution to the work.

Author declaration and disclosures: *The author does not have any commercial associations that may pose a conflict of interest related to this article.*

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AMERICAN MEDICAL WRITERS ASSOCIATION AMWA JOURNAL V38 N4 / 2023

ORIGINAL RESEARCH

Data Mining FDA Docket 2019-N-1482: Content, Sentiment, and Metadata

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ABSTRACT

The legal status of cannabis continues to evolve, raising challenges for medical writers who work in population health and drug safety. To guide messaging, research has investigated how the public perceives cannabis, often relying on surveys or "big data" analyses of social media. However, these methods can be costly. As a supplement, we explored comments posted to a United States Food and Drug Administration docket on cannabis science and risk, which may offer an accessible, purposive, cost-effective source of data. We applied a multipronged methodology that involved content analysis, sentiment analysis, and metadata analysis. The findings suggest that broad messaging on cannabis may have limited effectiveness. Instead, medical writers should design messages that emphasize the risks of particular products as well as express empathy for consumers suffering from specific conditions. Moreover, among other things, the findings suggest that medical writers should use the terms "cannabis" and "marijuana" intentionally, considering the implications of each. In the future, research should develop methods to further segment drug consumers demographically and psychographically, building on the methodology that we present here. This research may inform not just messaging but regulatory writing practices and state drug policies.

The legal status of cannabis has been debated in numerous countries, including the United States (US), where the legal cannabis industry may exceed $43 billion in sales by mid-decade.[1] There have also been changes in public attitudes. A recent survey by the Pew Research Center found that over the past decade, the number of US adults who oppose cannabis legalization has fallen 20 percentage points, from 52% to 32%.[2] Moreover, 9 out of 10 US adults now support the legalization of cannabis for medical or recreational use, raising numerous questions for public health.[3]

The US Food and Drug Administration (FDA) subsequently convened a hearing on May 31, 2019, to "obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds."[4] Although the in-person proceedings concluded at 6:00 PM that day, the discussion has continued through the comments posted to the hearing's docket. The docket comments are broadly accessible, excepting proprietary and other sensitive information.

Comments posted to federal dockets have received little attention from medical writers and researchers in adjacent fields. Yet, there are several reasons why these comments are potentially valuable. First, the commenters are invested in the legal status of cannabis, and thus their comments provide a form of purposeful sampling (see Palinkas et al.[5]). In aggregate, their comments, similar to social media posts, may texturize our understanding of how the public perceives cannabis, offering a quick and low-cost alternative to surveys.[6] Second, Regulations.gov, where FDA dockets are hosted, informs commenters that what they submit may be displayed there. The site relatedly informs commenters that, in addition to official agency uses, third parties may access or collect comments for their own purposes.[7-9] Third, the FDA has stated that comments "can, and do, influence agency decisions,"[10] potentially impacting the work of medical writers in regulatory settings.

Using a multipronged methodology, this study explored who the commenters are on FDA docket 2019-N-1482 and what they are commenting about. Our specific research questions were

1. What are common themes and concepts in the comments?
2. What sentiment is expressed in the comments?
3. How did the commenters self-identify, based on the demographic categories that the FDA provides?
4. What geolocations are the comments attached to?

The answers to these questions provided helpful insights into docket comments, suggesting ways that medical writers can gauge public perceptions of cannabis.

ISSN 2163-5315

METHODS

Our methods involved 3 general steps: scraping the data, clearing the data, and visualizing the data. We briefly explain each below.

Scraping the Data

Using a custom script in Python, we scraped all of the comments posted to the docket by January 2021 (n = 4,300). We also scraped commenter geolocation and demographic category (eg, individual consumers, industry representatives, health care professionals, members of government, etc.). Commenters can choose whether to include these metadata or not.

Cleaning the Data

This consisted of several sub-steps that are common in data analytics. We removed leading and trailing whitespace, standardized spellings (drug and chemical names, in particular), and filtered out stopwords. Our stopwords were honorifics "thanks," "thank you," and "sincerely" because these words convey phatic rather than substantive meaning in the data set. They also included prepositions (eg, "of," "to," "at") and coordinating conjunctions (eg, "so," "and," "but"), which tend to carry little semantic meaning.

For content analysis, we used the stemming algorithm in Leximancer, a data analytics program that is commonly used in health-related research.[11-14] For sentiment analysis, we lemmatized the data to optimize output from Valence Aware Dictionary and sEntiment Reasoner (VADER), as Symeonidis et al.[15] recommend.

Visualizing the Data

We visualized the data both demographically and psychographically. To do so, we applied content analysis, sentiment analysis, and what we called "metadata analysis." For content analysis, we uploaded the data set to Leximancer, as mentioned above. Leximancer calculates the presence and frequency of key concepts as well as their co-occurrence.[16(p8)] Concepts are clusters of terms that tend to "travel together" in a data set and, when grouped together as themes, maximize the relevancy of all the other words in a data set.[16(p11)] Based on the concepts it detects, Leximancer produces a heat map showing the relationships between themes and their underlying concepts as well as frequency. The former is indicated by the location of a theme or concept on the map and the latter by its color: the "hotter" the color (with red being the hottest, purple the coldest), the greater the frequency.

For sentiment analysis, we used VADER, which takes a "bag of words" approach. That is, it analyzes lexical features that, based on their meanings, are typically perceived as positive, negative, or neutral.[17] In our study, we used VADER to calculate a compound sentiment score for each docket comment and then average a final score for the whole data set. For both subjectivity and polarity, sentiment scores are normalized between –1.0 (negative sentiment) and 1.0 (positive sentiment).[17]

For metadata analysis, we focused on how commenters self-identified as well as where the comments were geolocated. Specifically, we quantified the frequency of each FDA demographic category, each country attached to the comments, and each US state attached to the comments. We charted these findings through Microsoft Excel and Tableau.

RESULTS

What Are Common Themes and Concepts in the Docket Comments?

Our content analysis with Leximancer identified 10 common themes in the data set, which are displayed in Figure 1.

The most common theme was CBD, referring to cannabidiol (10,954 occurrences). Its primary concept, CBD, tended to co-occur with oil (2,093 co-occurrences), use (1,902), take (1,260), helped (1,110), relief (419), milligrams (364), daily (340), doctor (255), and dose (243).

The next most common theme was pain (8,138 occurrences). Its primary concept, pain, tended to co-occur with chronic (537 co-occurrences), anxiety (519), life (400), sleep (369), work (309), arthritis (280), able (275), tried (251), started (230), better (214), year (182), depression (175), old (121), days (118), down (101), and symptoms (99).

The third most common theme was medical (6,883 occurrences). Its primary concept, medical, tended to co-occur with effects (305 co-occurrences), prescription (175), need (167), people (154), issues (112), conditions (106), patients (97), cause (74), treatment (73), active (38), and disease (34).

The fourth most common theme was products (6,188 occurrences). Its primary concept, products, tended to co-occur with hemp (633 co-occurrences), consumer (395), testing (288), benefits (279), supplement (273), extract (266), pharmaceutical (136), food (266), companies (245), potential (190), and form (133).

The fifth most common theme was health (5,591 occurrences). Its primary concept, health, tended to co-occur with believe (69 co-occurrences), levels (67), access (58), children (57), consider (56), natural (49), available (45), allow (43), provide (42), medicine (42), THC or tetrahydrocannabinol (39), and quality (35).

The sixth most common theme was cannabis (5,043 occurrences). Its primary concept, cannabis, tended to co-occur with regulations (288 co-occurrences), plant (269), FDA (231), support (196), compounds (140), safety (95),

public (91), industry (85), market (81), cannabinoids (74), information (53), data (51), and based (35).

The seventh most common theme was drug (4,197 occurrences). Its primary concept, drug, tended to co-occur with legal (97 co-occurrences), control (70), alcohol (49), research (43), studies (40), states (33), and government (33).

The eighth most common theme was time (2,824 occurrences). Its primary concept, time, tended to co-occur with seizures (53 co-occurrences), family (36), body (29), and cancer (20).

The ninth most common theme was marijuana (1,833). Its primary concept, marijuana, tended to co-occur with substance (55), law (49), DEA or Drug Enforcement Agency (43), respondent (31), and money (20).

The tenth most common theme was months (878 occurrences). Its primary concept, months, tended to co-occur with night (25).

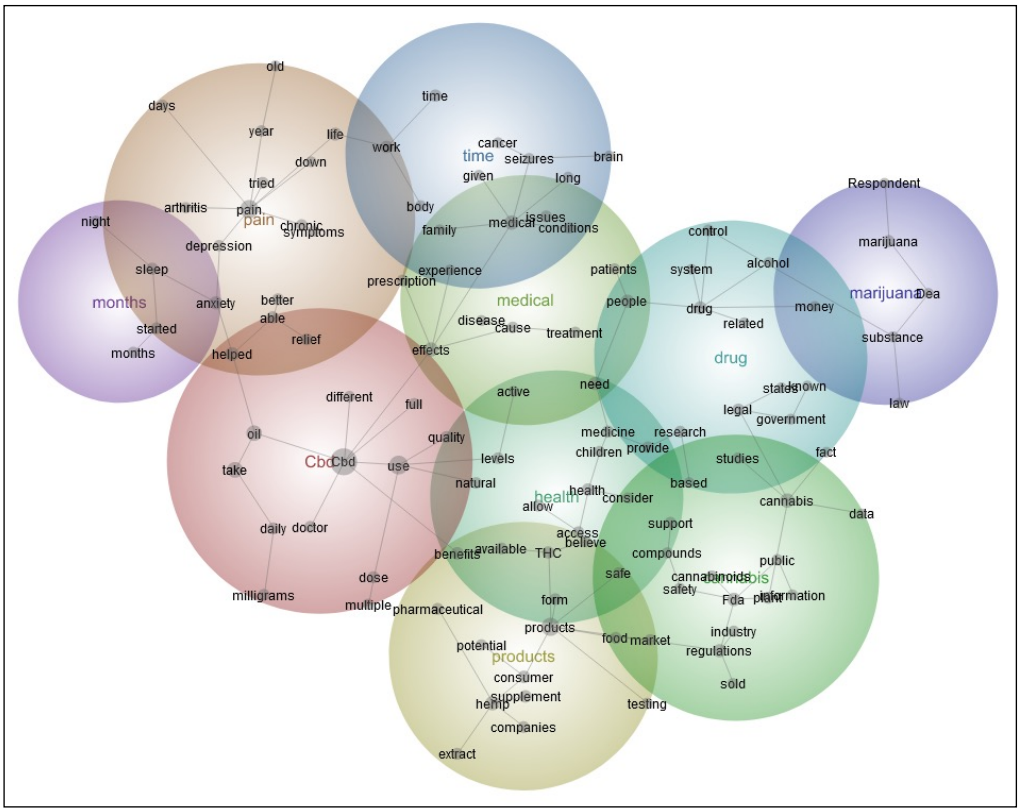

Figure 1. A heat map generated by Leximancer showing the relationships between themes and their underlying concepts as well as frequency. Relationships are indicated by the location of a theme or concept, and frequency is indicated by hue.

What Is the Sentiment in the Comments?

We found that the data set had a mean subjectivity score of 0.418, with a standard deviation of 0.190. The data set had a mean polarity score of 0.121, with a standard deviation of 0.167.

How Did the Commenters Self-Identify?

The FDA docket did not require commenters to self-identify by selecting a demographic category. In our sample, only 467 commenters did choose to self-identify: as individual consumers (81 commenters), health professionals (8), international public citizens (1), or representatives of various organizations.

Most commenters affiliated with an organization chose the most general demographic categories, such as other organizations (157 commenters), association (103), or private industry (32). Some were more specific, self-identifying as representatives of the drug industry (23), a consumer group (16), the food industry (8), a health care association (5), or international industry (4). Some commenters self-identified as representatives of local (1), state (2), federal (3), or other government (15) as well as academia (5) or the media (2). See Figure 2.

What Geolocations Are the Comments Attached to?

The majority of comments were not geolocated, but slightly more than two-fifths (1,821 comments) were. A few comments were reportedly from a geolocation outside of the US: the United Kingdom (3), Canada (3), Australia (2), Norway (1), South Korea (1), or Germany (1).

Most were from a geolocation in the US, as displayed in Figure 3. All 50 states were represented, and so was the District of Columbia. The states with the most comments were California (183 comments), Texas (152), and Florida (128), Missouri (82), New York (73), North Carolina (66), Illinois (62), Colorado (57), Kansas (57), and Wisconsin (54). Several other states had at least 50 comments: Georgia (52 comments), Oklahoma (51), and Virginia (50).

Eight states had fewer than 50 comments but at least 30: Washington (46 comments), Arizona (43), Michigan (41), Ohio (40), Massachusetts (35), Pennsylvania (35), Oregon (32), and Tennessee (30).

Nineteen states and the District of Columbia had fewer than 30 comments but at least 10: New Jersey (29 comments), Maryland (27), South Carolina (26), Indiana (24),

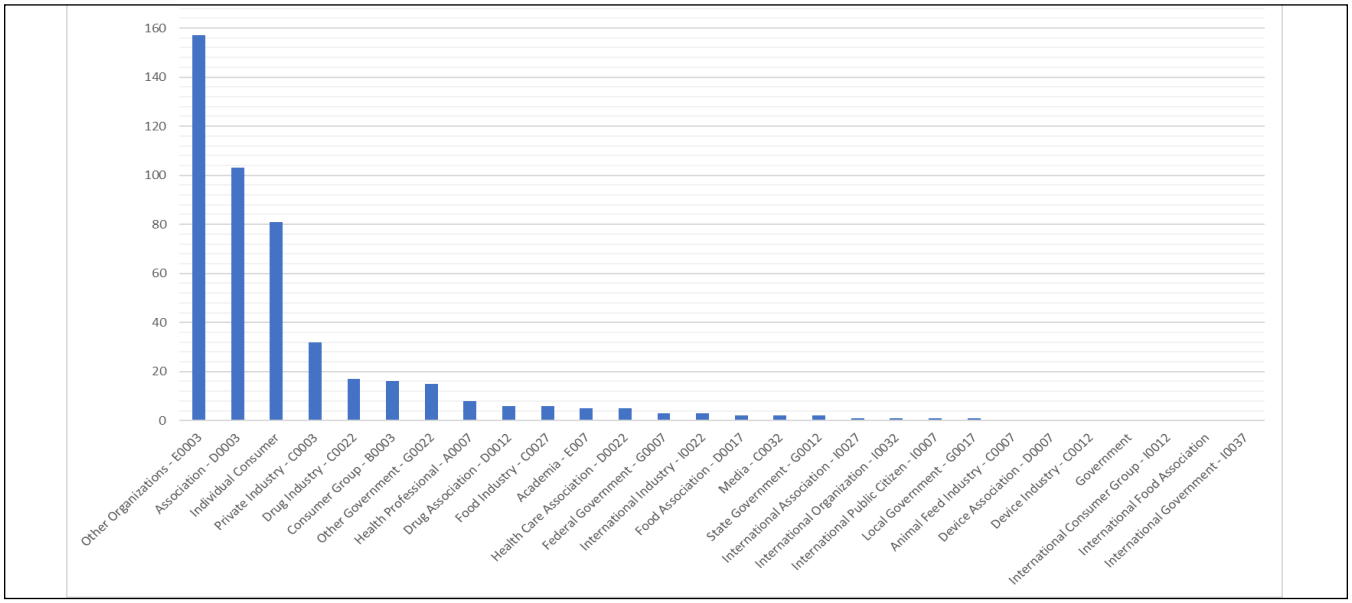

Figure 2. How the commenters self-identified, based on the demographic categories provided by the FDA (n = 467).

Kentucky (24), Arkansas (23), the District of Columbia (23), Alabama (22), Minnesota (22), Nebraska (20), Connecticut (19), Nevada (19), Utah (19), Iowa (17), New Mexico (15), Louisiana (11), Montana (11), Vermont (11), Idaho (10), and New Hampshire (10).

The states with the fewest comments were Mississippi (9 comments), West Virginia (9), Hawaii (8), Rhode Island (8), Alaska (6), Wyoming (6), Maine (5), North Dakota (3), South Dakota (3), and Delaware (2). The average number of comments per state was 35.5 with a standard deviation of 36.4.

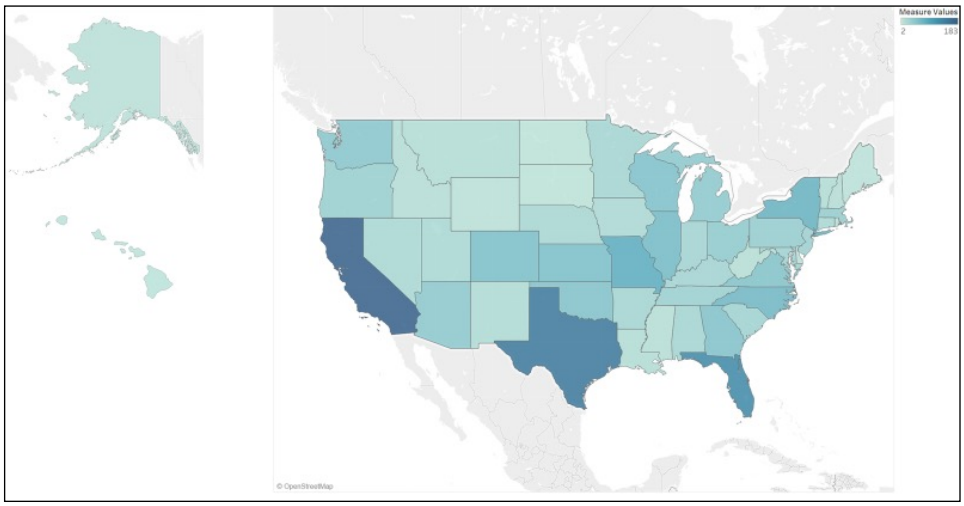

Figure 3. The geolocation of comments in the data set, specific to the US (n = 1,810). Darker shades indicate a greater number of comments.

DISCUSSION

Prior "big data" research that explores public perceptions of cannabis has generally focused on social media posts.[18-28] Expanding on this research, our study investigated public comments to FDA docket 2019-N-1482, applying content analysis, sentiment analysis, and metadata analysis in ways that may be relevant for medical writers.

The content analysis suggests that the commenters were less concerned with cannabis in the abstract and more concerned with specific products and symptoms. Of particular concern were CBD and hemp and the treatment of pain, anxiety, and sleep issues. This finding may have relevance for public health messaging: rather than targeting cannabis in general, messages might be more effective if they discuss the risks associated with particular products or if they express empathy for consumers suffering from particular symptoms or conditions.

The concepts "use" and "take" appeared frequently in the data. This makes sense, given that a large share of commenters who chose a demographic category self-identified as individual consumers. Future messaging should strategically employ different verbs, such as "use" and "take," so that medical writers can evaluate the effects. On first glance, "take" may have a stronger association with health and medical discourses. "Use" may have a stronger association with illicit or recreational activity. Such associations may have a significant influence on a message's overall effectiveness.

The content analysis also suggests that cannabis and marijuana have different semantic orientations in the data

set. "Cannabis" was associated with concepts that seem regulatory and scientific, such as safety, public, regulations, compounds, industry, cannabinoids, and data. "Marijuana" may have a more legalistic or punitive orientation, considering its co-occurrences with concepts like substance, law, and money. Future studies could test how participants respond to messages about "cannabis" compared with messages about "marijuana." In the meantime, medical writers should use the 2 terms intentionally, considering the possible implications of each. Although common in everyday speech, "marijuana" may carry more stigma.

The sentiment scores indicated positive polarity and subjectivity. The polarity score suggests that commenters generally had neutral or favorable views of cannabis, which should be confirmed through additional research. The subjectivity score suggests that commenters tended to express personal feelings, opinions, and preferences. It is unknown whether FDA officials will consider these subjectivities to be "sound grounds" for decision-making.10 Because the number of comments per state was so variable (the average being 35.5 with a standard deviation of 36.4), we did not calculate sentiment scores by state. A richer level of granularity that allows comparisons across states would improve on the methodology that we reported here. That granularity could also support inter- and intra-state policy evaluations, suggesting how cannabis policies may have "moved the needle."

The metadata analysis was small scale, as only 10.9% of the comments indicated the commenters' demographic category. More than half of these comments were from other organizations or associations, and slightly less than a fifth were from individual consumers. Because these demographic categories are self-reported, they cannot be fully verified. Future studies might develop techniques of categorizing demographic information in the comments themselves, beyond the limited categories provided by the FDA. It would be interesting, for instance, to examine how sentiment may vary by occupation, education level, income, age, and gender. The findings could support more targeted medical and regulatory communication regarding cannabis as well as policy development.

Geographically, the metadata analysis indicated that the docket has attracted comments from all 50 US states and the District of Columbia as well as 6 countries besides the US. More than half of the comments were not geolocated. Of those that were, about a third came from just 5 states: California, Texas, Florida, Missouri, and New York. Because most comments were not geolocated, it is not possible to determine the representativeness of the docket comments. Indeed, the comments may not be representative of public opinions toward cannabis writ large. Yet, the median number of comments per state and standard deviation suggests considerable geographic variation in the docket's "public participation" and "open exchange of ideas."[29]

CONCLUSION

At minimum, federal docket comments seem well suited to hypothesis generation based on themes/concepts, sentiment, and metadata. Future studies should explore ways to further segment drug consumers demographically and psychographically, building on the multipronged methodology we described here. These studies may inform not just messaging but regulatory communication and state drug policy, supporting the work of medical writers.

Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

FROM THE PRESIDENT

R. Michelle Sauer, PhD, ELS / 2023-2024 AMWA President

To the AMWA Membership,
I want to begin my first article as president with thanks. Thank you to the membership and the nominating committee for their trust; it places me in a state of grace.

Shortly after being hired at UTHealth in 2009, I joined the American Medical Writing Association, and that is where I found "my people." In this community, I have grown as a professional and as a human because of the amazing people who volunteer their time and expertise to this organization. I have been mentored by incredibly talented individuals, and I am honored to have served at the chapter and national level. I am now truly excited to begin my term as your president.

As I start my term, I am reminded of how diverse AMWA is. We are not one thing. We are editors, writers, and graphic artists. We are in regulatory, in academia, in education. We span the continent and the globe. In fact, even as individuals we are not one thing; often our work and experience allows us or forces us to be 5 things at once. This internal diversity is a strength, and it fosters the breath of education that AMWA is able to offer. As an organization, we aim to understand and harness our diversity to enable an inclusive and equitable environment. We want every member to feel welcomed by AMWA, and I am very thankful for the volunteers of the Diversity and Inclusion Assessment Task Force, led by Dr Gail V. Flores, who gathered and analyzed member data and survey results focused on this topic. I am also appreciative to the AMWA staff and board members who have dedicated considerable time this past year to see and define the AMWA way of diversity, equity, and inclusion (DEI). To pursue our mission of promoting excellence in medical communication, we must be fearless. We will continue to recruit and retain members with a variety of backgrounds, experiences, and expertise. In the year ahead, I hope to see the formation of a special DEI committee that will support the Board of Directors (BOD)'s initiatives to foster the organization's strategic growth.

Education is the heart of AMWA, and as the work to ensure fantastic conferences and online learning continues, I am thankful for the members and leaders within the Education Committee who have been diligently working to ensure timely webinars, updated workshops, and new certificates. I am also excited to see the launch of the Health Communication Task Force; its work will bring honor to Lori L. Alexander's legacy.

With the growth in the medical communication field, there has also been a greater need for medical communication education programs. AMWA has focused considerable time and effort into education offerings for the full spectrum of medical communicators, and these offerings will continue to expand and be refined.

ISSN 2163-5315

New rules and guidance may need to be established and updated to meet the changes and opportunities brought about by AI.

One of the growing needs of our membership is education and guidance regarding artificial intelligence (AI). Medical communicators will need to adapt, evolve, and find an ethical path forward. New rules and guidance may need to be established and updated to meet the changes and opportunities brought about by AI. Recent blogs on AI and authorship are available on the AMWA website, and many of the sessions at the annual conferences are excellent resources. I look forward to working with leaders to build upon these initial efforts. At the same time, criticism of our profession has once again surfaced in the peer-reviewed literature. Although some throw rocks at things that shine, it is our job to do more than shake it off. I look forward to working with the BOD and subject matter experts in AI and in medical communication ethics so that we continue to assess and meet the needs of our membership. We will protect our reputations and identify and build needed tools.

As we look to the future, I want to pause and think about how we got here. If you met me 20 years ago, you would meet a graduate student who was determined to make a contribution to this world. Within 5 years, I was a postdoc with burnout. Fortunately, around that time, a grad school friend invited me to join their medical writing team, and that is when I found "my thing." I left the bench and upgraded my laptop. Although I have held many different titles (assistant professor, senior research scientist, research liaison), my favorite professional title is medical communicator. Although many of you have similar stories of winding paths to find this unique career niche, some of you have graduated from programs specifically designed to train medical communicators. Although our field and our education continue to evolve, AMWA has consistently been there to lead medical communication professionals, and I hope we are all dedicated to continuing that mission.

The year ahead will be busy. We will add and refine educational content, we will grow in numbers and diversity, and we will overcome obstacles and increase equity with innovative solutions. The goals I've outlaid are possible because of the incredible board members, chairs, committees, staff, and volunteers. As a member, I ask each of you to find a way to connect with AMWA. Attend a local chapter event, offer to join a committee, or share your expertise on Engage or through a journal article. It is going to be a great year ahead. Are you ready for it?

Author declaration and disclosures: *The author notes no commercial associations that may pose a conflict of interest in relation to this article.*

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AMWA NEWS

Introducing the 2023–2024 Board of Directors

R. Michelle Sauer, PhD, ELS / 2023–2024 AMWA President

Article III of the American Medical Writers Association's bylaws states that a Board of Directors (BOD) will manage and control the affairs, property, and business of the organization. The BOD is responsible for approving the budget, the slate of nominees for elected office, and any proposed amendments to the Constitution or Bylaws. It also approves committees, work groups, and task forces and fulfills such other duties as are specifically mentioned in the Constitution and Bylaws and as required by law. Thus, the members of the BOD carry considerable responsibility.

In alignment with AMWA Bylaws, the BOD includes elected officers (President, President-Elect, Secretary, Treasurer, Immediate Past President), an executive director, a chair of the chapter advisory council, and at least 5 appointed at-large directors. The number of members on the BOD during the governance year shall be no less than 12 and no more than 17.

I am pleased to introduce the 2023–2024 BOD. This group of professionals reflects characteristics of the member population and has volunteered their time and talent to meet, discuss, and take action on items as they pertain to the organization.

At its September 2023 meeting, the BOD approved the following individuals to serve as at-large directors for the 2023-2024 term:

- Joan Affleck, MBA, ELS
- Sarah Dobney, MPH
- JoAnna Pendergrass, DVM
- Genevieve Walker, PhD
- Jennifer Minarcik, MS
- Katrina R. Burton, BS
- J. Kelly Byram, MS, MBA, ELS
- Qing Zhou, PhD, ELS

The BOD also approved Erik MacLaren, PhD, as the chair of the chapter advisory council (a voting member of the BOD).

AMWA 2023–2024 Officers:

- **President:** R. Michelle Sauer, PhD, ELS
- **President-Elect:** Shawn Watson, PharmD, PhD, BCPS, RPh, BSPharm
- **Secretary:** Kimberly Korwek, PhD
- **Treasurer:** Julie Phelan, MD, MBA
- **Immediate Past President:** Elise Eller, PhD
- **AMWA Executive Director:** Susan Krug, MS, CAE (ex officio, nonvoting)

The 2023–2024 BOD began its service on October 28, 2023, at the conclusion of the 2023 Annual Business Meeting at the 2023 Medical Writing & Communication Conference in Baltimore, Maryland.

The American Medical Writers Association bylaws can be read at the following link: https://cdn.ymaws.com/www.amwa.org/resource/resmgr/about_amwa/Bylaws/AMWA_Bylaws_November_2017.pdf

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CALENDAR OF MEETINGS

Medical Writing & Communication Conference
OCTOBER 23-26, 2024
NEW ORLEANS, LA

Trends and Opportunities for Medical Communicators

International Society for Medical Publication Professionals
"2024 European Meeting of ISMPP"
January 23-24, 2024
London, UK
https://www.ismpp.org/european-meeting

Alliance for Continuing Education in the Health Professions
"The Alliance 2024 Annual Conference"
February 5-8, 2024
New Orleans, LA
https://www.acehp.org/Registration

American Association for the Advancement of Science
"Toward Science Without Walls"
February 15-17, 2024
Denver, CO
https://meetings.aaas.org/

Regulatory Affairs Professionals Society
"RAPS Global Regulatory Strategy Conference"
March 5-7, 2024
Linthicum Heights, MA
https://www.raps.org/events/raps-global-regulatory-strategy-conference-2024

Drug Information Association
"DIA Europe 2024"
March 12-14, 2024
Brussels, Belgium
https://www.diaglobal.org/en/flagship/dia-europe-2024

American Copy Editors Society/ACES: The Society for Editing
"ACES 2024 San Diego: Unleashing Creativity"
April 4-6, 2024
San Diego, CA
https://aceseditors.org/conference/2024-san-diego-1

The Association of Clinical Research Professionals
"ACRP 2024"
May 3-6, 2024
Anaheim, CA
https://acrpnet.org/event/acrp-2024/

Council of Science Editors
"2024 CSE Annual Meeting"
May 4-7, 2024
Portland, OR
https://www.councilscienceeditors.org/annual-meeting

European Medical Writers Association
"Valencia 2024"
May 7-10, 2024
Valencia, Spain
https://www.emwa.org/conferences/future-conferences/

Society for Scholarly Publishing
"Inflection Point: Setting the Course for the Future of Scholarly Communication"
May 29-31, 2024
Boston, MA
https://customer.sspnet.org/SSP/ssp/AM24/Home.aspx

Drug Information Association
"DIA 2024 Global Annual Meeting"
June 16-20, 2024
San Diego, CA
https://www.diaglobal.org/en/flagship/dia-2024

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