by Carolyn Gretton

The Devil is in the Details

The ongoing effort by accreditation and monitoring groups to separate commercial interests from continuing medical education (CME) funding appears to be raising as many questions as answers.

It has been a year since Pfizer rocked the CME sector by announcing it would no longer fund physician CME programs provided by third-party medical education and communications companies. Other major pharma companies quickly followed with pledges to either end third-party funding or to disclose when third-party funding was used in their CME activities. On the provider side, communications companies have spun off their medical education units in an effort to establish a clear boundary between their promotional businesses and their CME operations.

These moves were prompted mainly as a result of revised guidelines issued by the Accreditation Council for Continuing Medical Education (ACCME) calling for more stringent monitoring and disclosure of commercial involvement in CME.

ACCME, a nonprofit accrediting body for organizations that produce CME in the United States, provides recommendations for the funding through its Standards for Commercial Support. Among other requirements, the ACCME standards mandate that all of those involved in the development and presentation of CME activities must disclose relevant financial relationships with commercial interests, and that anyone who refuses to disclose is disqualified from planning or teaching CME activities.

However, experts note that the revised ACCME guidelines are only part of the impetus behind the changes roiling the CME sector. Chris Bogan, CEO of Best Practices, notes that there are a number of factors behind the recent decline in overall CME funding, not the least of which is the persistently sluggish U.S. economy, which has caused companies to rethink overall funding at all levels.

"It's not just the Pfizer issue: it's Pfizer plus the overall public debate, the scrutiny, the regulatory issues, the change in healthcare," Mr. Bogan says. "Even support for larger scientific societies and medical associations that deliver forms of CME is being closely scrutinized."

Some of this scrutiny is coming from the government. During a hearing on conflicts of interest in CME held in July by the U.S. Senate Special Committee on Aging, ACCME Chief Executive Murray Kopelow, M.D., outlined some of the steps taken by the ACCME in recent months to strengthen its standards enforcement and increase the system's transparency and accountability. These include the development of a Web portal for collecting up-to-date program content and financing data from CME providers and an acceleration of its enforcement process for accredited CME providers found to be out of compliance with Standards for Commercial Support.

Mr. Bogan views the greater transparency as a positive in the long run, but observes that in the short term, it has created funding pressures on smaller organizations and projects that now have to follow a much more formalized grant process.

"Smaller projects — $1,000 or $2,000 activities, talks, or roundtables, for example — are being squeezed because of the greater effort involved in having to make a grant request," he says. "At that level, it probably discourages some groups and types of programs from even applying for funding."

CONTROVERSIAL PROPOSAL

Earlier this year, ACCME solicited feedback on its proposed policy of differentiating CME programs that include relationships with the industry from those that do not. The proposal includes the creation of a new designation and review process for providers that wish to identify their program of CME as one that does not use funds from commercial interests that have been donated to support continuing medical education, such as commercial support-free. Standards suggested for this designation include not accepting any commercial support for any CME activity, or any part of a CME program, and not using funds from advertising or promotion, paid by an ACCME-defined commercial interest, to underwrite the costs of CME.

Chris Bogan
Best Practices

If CME is differentiated by funding, such as commercial support-free or commercial-supported, then **everyone would be able to clearly see if there are quality and content-type differences between different programs**.

A common theme emerging from the comments ACCME published on its Website is that while identifying commercial support-free CME is a good idea, its execution may prove difficult.

In his comment to ACCME on the proposal, Jeffrey Uppington, M.B.B.S., a member of the Cali-

Sandra Dennis
BIO

Mark Bard
Manhattan Research

Rather than pulling the plug on a vital source of CME funding, the primary beneficiaries of CME — **physicians and patients — would be best served by continued improvements to course availability, offerings, and content** through increased collaboration among medical and academic organizations, the pharmaceutical industry, CME providers, and accreditation bodies.

A designation process suggesting that there is an **unsubstantiated problem with CME activities could reduce learner participation**, resulting in reduced interest in commercial support for CME and a decrease in overall activities.

fornia Society of Anesthesiologists and a faculty member of an academic department that organizes annual CME review courses, notes: "It is not clear in the proposal whether the designation applies only to a specific program offered, or if a provider that offers multiple CME programs would be regarded as polluted for all programs, even if unrestricted educational funding was received only for a single program.

"In either event, the CSA and I believe these restrictions would limit our ability, as an ACCME-accredited CME provider, to provide high-quality and relevant CME programs to our members and to the practitioners our review course serves," Dr. Uppington adds.

Mary Manna Anderson, president of HLS, a CommonHealth company, says today, 90 of 125 U.S. academic medical centers now have policies regarding physician-industry interactions.

"Such policies limit activity, as well as compensation, to an average of $15,000 to $20,000 per pharma company — not brand," she says. "Pharma companies frequently engage national opinion leaders as consultants, advisors, and, to some extent, faculty trainers and speakers. These new dollar limits will necessitate that companies engage national opinion leaders more strategically and engage more regional and local opinion leaders in private practice." (For more information, please see the VIEW on Increased Regulation and Mature Web Technology: Fertile Ground for a New Generation of Clinical Opinion Leader Engagements.)

In her comment to ACCME, Sandra J.P. Dennis, deputy general counsel for healthcare for the Biotechnology Industry Organization (BIO), expresses concern that creating this kind of stratification of CME programs could impact the quality and availability of CME as a whole.

"A designation process suggesting that there is an unsubstantiated problem with these activities could reduce learner participation, resulting in reduced interest in commercial support for CME and a decrease in overall activities," Ms. Dennis notes. "BIO agrees with the ACCME's belief that CME is a strategic asset, and therefore we encourage the ACCME to focus on how to meet this goal through the current accreditation process."

Mr. Bogan's view on the proposal is twofold. "I do like the idea of the designation because I think it

THOUGHT LEADERS

MARY MANNA ANDERSON. President, HLS, CommonHealth's founding medical education unit, excels in the development and dissemination of scientific messages by employing new market approaches to connect the insights of opinion leaders with the clinical realities of practicing physicians. For more information, visit commonhealth.com/hls.

MARK BARD. President, Manhattan Research, a Decision Resources Inc. company that offers market research and advisory services focused on the digital trends shaping the future of consumer and physician marketing. For more information, visit manhattanresearch.com.

CHRIS BOGAN. CEO, Best Practices LLC, a research, consulting, database, and publishing firm focused on the pharmaceutical, biotech, medical device, and healthcare industries. For more information, visit best-in-class.com.

SANDRA J.P. DENNIS. Deputy General Counsel for Healthcare, Biotechnology Industry Organization (BIO), which provides advocacy, business development, and communications services for more than 1,200 biotechnology members worldwide. For more information, visit bio.org.

EZRA ERNST. General Manager, Medscape LLC, an accredited provider of continuing medical education. For more information, visit medscapecme.com.

MURRAY KOPELOW, M.D. Chief Executive, the Accreditation Council for Continuing Medical Education (ACCME), a nonprofit group focused on the identification, development, and promotion of standards for quality continuing medical education used by physicians. For more information, visit accme.org.

JACK LEWIN, M.D. CEO, American College of Cardiology, a nonprofit medical society that leads the formulation of health policy, standards, and guidelines; supports cardiovascular research; and provides professional education programs. For more information, visit acc.org.

KAREN SULLIVAN. Editor/Writer, ProCom, part of CommonHealth, which creates and delivers unique domestic and global educational programs across multiple channels that maximize participation and retention. For more information, visit commonhealth.com/procom.

JEFFREY UPPINGTON, M.B.B.S. Director, District 8, California Society of Anesthesiologists, a physician organization dedicated to promoting the highest professional standards in anesthesiology, to fostering excellence through continuing medical education, and to serving as an advocate for anesthesiologists and their patients. For more information, visit csahq.org.

MICHAEL ZILLIGEN. General Manager, ProCom, a part of CommonHealth, that creates and delivers unique domestic and global educational programs across multiple channels that maximize participation and retention. For more information, visit commonhealth.com/procom.

ViewPoint

Mary Manna Anderson
HLS

Dollar limits will necessitate that companies engage national opinion leaders more strategically and engage more regional and local opinion leaders in private practice.

Karen Sullivan
ProCom

With the advent of the Internet, medical education **developers can deliver information faster than ever**.

Ezra Ernst
Medscape LLC

More than ever before, **physicians are reaping the benefits of advances in technology and education and, consequently,** are increasingly recognizing the value that CME affords them in their daily practices.

Michael Zilligen
ProCom

The added benefit of instant access to a wealth of specialized subject matter delivered using many different methods provides **a time-saving and cost-effective alternative** to traditional learning environments.

might be helpful in evaluating whether this hobgoblin of concerns about commercial funding and the impact on CME is real or just paranoia," he says. "If CME is differentiated by funding designation, such as commercial support-free or commercial-supported, then everyone would be able to clearly see if there are quality and content-type differences between programs created through the different funding designations. I suspect that there's a lot more concern about this conspiracy of funding influencing program quality and content than I have ever found to be the case, so I like the idea of shining a light on it to dispatch any concerns."

However, he cautions, the process could backfire in such a way that the adverse effect would be greater than the benefit.

"The designation could mean commercially funded programs that aren't available anywhere else could be eliminated from consideration because people might begin to worry that such funding means the program is compromised," he observes. "This would slow the information diffusion process, the education process, and could cause the starvation of funds for a smaller set of program types. I think we would all ultimately lose out if this were the case."

PHYSICIANS' PERSPECTIVE

Despite ongoing concerns about the potential bias of commercially funded CME, feedback from recent surveys conducted by ACCME and consulting groups show that physicians don't appear overly troubled by it. For example, only 9% of U.S. physicians surveyed for a recent Manhattan Research study said they oppose commercial support for CME funding, and only 8% of physicians who participated in CME believe that it is biased. In fact, if commercial support is halted, nearly half of the physicians surveyed said they would decrease their use of CME.

According to Ezra Ernst, general manager, Medscape LLC, more than ever, physicians are reaping the benefits of advances in technology and education and, consequently, are increasingly recognizing the value that CME affords them in their daily practices. This is evidenced by the 385% growth rate observed in online CME over the last five years.

"The value of CME to practicing physicians seems obvious," he says. "Precisely as the practice of medicine has become more complex, today's physicians have diminished time to devote to learning about new disease management strategies. The broad accessibility of high-quality, interactive CME activities offers them unparalleled access to insights from key opinion leaders and myriad learning opportunities. (For more information, please see the VIEW on The Value of CME.)

In a prepared statement announcing the study findings, Manhattan Research President Mark Bard observed: "While there's been debate around the value of industry-supported CME, as our study reveals, it's important to listen to the voice of the majority of physicians. Rather than pulling the plug on a vital source of CME funding, the primary beneficiaries of CME — physicians and patients — would be best served by continued improvements to course availability, offerings, and content through increased collaboration among medical and academic organizations, the pharmaceutical industry, CME providers, and accreditation bodies."

Physician feedback to ACCME's proposed "commercial support-free" label for CME appears to reinforce this view. In its comment to ACCME, The American Academy of Family Physicians (AAFP) notes the proposed designation "conflicts with ACCME's recent position on external funding and creates a perception of quality CME based on a hierarchy of funding source."

The AAFP comment further observes that an ACCME-commissioned study published in June 2008 found no evidence that commercial support-free accredited CME is superior to CME funded with external support.

Interestingly, research conducted by Best Practices seems to indicate that many medical professionals believe commercial involvement is necessary if CME is to thrive.

"We did one study reaching out to prestigious medical schools and teaching institutions that had programs that were supported commercially," Mr. Bogan notes. "And that quick little poll of small but elite subgroups said that if all commercial funding were cut off, they thought probably anywhere from 60% to 80% of their funding for certain types of programs would disappear."

At a recent conference on industry support of CME co-sponsored by the Center for Medicine in the Public Interest (CMPI) and the Coalition for Healthcare Communications, Jack Lewin, M.D., CEO of the American College of Cardiology, explained that organizations such as his emphasize transparency of industry involvement in CME programs.

"We make certain that CME activity is absolutely firewalled with a degree of scrutiny," Dr. Lewin says. "Were we not to have these additional services, which we believe rapidly advance the education of our members and the translation of

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Jaime Pfaff
Executive Creative Director
Corbett Worldwide

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science to the point of care, the patients and doctors who serve them will be harmed."

CHANGE IS CONSTANT

It is always difficult to forecast the direction of a sector as dynamic as CME. In the short term, Mr. Bogan believes that the combination of a sluggish economy and increasingly restrictive funding guidelines could result in a shakeout in the sector.

"The funding shortages will probably be felt in particular camps and quarters of the CME sector, especially the smaller firms," he says. "Some really good CME vendors could disappear just because they were small boutique companies that couldn't overcome the market pressure."

Aside from the continued debate on commercial funding, Mr. Bogan believes the greatest challenges facing CME in the next year or two include demonstrating the value and positive impact of CME and optimization of CME delivery.

Michael Zilligen, general manager of ProCom, a CommonHealth company, says education has changed forever in the wake of the Internet, which has made information available to more people than ever before.

"In medical education, the added benefit of instant access to a wealth of specialized subject matter delivered using many different methods provides a time-saving and cost-effective alternative to traditional learning," he adds. (For more information, please see the VIEW on Adult Distance Learning in Promotional Education Programs.)

Mr. Bogan contends that there is a general concern about the quality of CME programs and how educational impact can be demonstrated, which is articulated most coherently by the biopharma side that funds it.

With most CMEs still favoring the in-person model of delivery, Mr. Bogan says the next step is broader adoption of technology.

"We need to discover how to use technologies to deliver CME at a lower cost and potentially with more flexibility and higher quality, while helping to advance the practice of medicine," he says.

Karen Sullivan, editor/writer, ProCom, a CommonHealth company, says with the advent of the Internet, medical education developers can deliver information faster than ever.

"Taking a cue from the success of online degree programs, today's education programs use the power of the Internet to reach countless HCPs, and increase knowledge retention by blending electronic media with the methodologies of adult distance learning," she says. (For more information, please see the VIEW on Adult Distance Learning in Promotional Education Programs.) ✦

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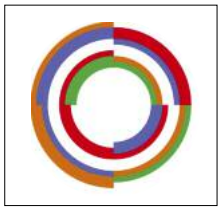

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SPECIAL FEATURE **VIEW ON MED ED**

by Carolyn Gretton

Clearer Guidelines

In March 2009, the ACCME added a number of clarifications to its guidelines on commercial involvement in CME and its impact on CME accreditation in response to questions from accredited CME providers seeking CLARIFICATION ON THE ISSUE OF ALLOWING EMPLOYEES OF COMMERCIAL INTERESTS TO PLAN AND/OR TEACH INSIDE ACCREDITED CME.

For example, some providers were confused as to whether industry employees could submit abstracts for poster sessions inside accredited CME, while others sought clarification around education on medical devices that might require the technical skills of an industry employee. Here is a sampling:

Q ***Can employees of commercial interests serve as planners or speakers in ACCME-accredited CME activities?***

A If the content of CME that the employee of the commercial interest controls relates to the business lines and products of its employer — **no**. If the content of CME that the employee of the commercial interest controls **does not** relate to the business lines and products of its employer — **yes**.

Q ***Can we offer accredited CME activities on research that was controlled in some way by a commercial interest, either through funding, collaboration, or involvement of the commercial interests' staff in the research itself?***

A Yes, as long as the CME activity complies with the ACCME's accreditation criteria, including the ACCME Standards for Commercial Support. It is understood and accepted that industry conducts its own research and that industry partners, as funder or collaborator, in research projects. An important step in the translation of discovery to practice is the dissemination of the results of this research. There are several layers of internal and external controls already in place to manage the conduct of research (e.g., Institutional Review Boards, government agencies) and the dissemination of results (e.g., editors, peer review, international standards). The ACCME does not intend to interfere with these carefully managed phases.

However, when an organization chooses to base its CME content on research the organization assumes responsibilities related to CME, including compliance with the ACCME Standards for Commercial Support. The CME content (not the research that has already taken place or is taking place) cannot be controlled by a commercial interest. As an example, industry employees cannot deliver oral presentations and cannot author enduring materials that are accredited CME if the CME content relates to business lines or products of their employer. ✦

Source: The Accreditation Council for Continuing Medical Education. For more information, visit accme.org.

Selected responses to the ACCME's proposed "commercial support-free" designation

Cost Prohibitive

"As a small organization, I feel that commercial-free rules have a more significant impact on us than larger organizations. As I look to create technology-based educational products, the cost is high. I have been quoted $25,000 to $50,000 and more.

We can never make this cost up in sales. We also don't have the ability to do the work in house or with volunteers."

— Unidentified accredited CME provider, in response to ACCME's proposed "commercial support-free" designation.

Out of Business

"I think this policy would damage the providers that continue to receive any commercial support in any amount.

I have seen CME grant funding decrease by $30,000 in the last two years for my program; I predict by next year, we will not be receiving any commercial support anyway."

— Unidentified accredited CME provider, in response to ACCME's proposed "commercial support-free" designation.

A Funding Distinction

"The AAFP objects to the use of such a distinct designation, which implies that CME funded through use of commercial financial support is 'tainted' relative to CME funded solely by learners or through other external support including government funds, private foundations, or other interests."

— The American Academy of Family Physicians, in response to ACCME's proposed "commercial support-free" designation.

Perpetuating Assumptions

"It is unclear what concern a new category of CME would seek to address. If the ACCME is concerned about a perception of bias (rather than actual bias), it seems that creating a distinct CME category without commercial support would serve only to perpetuate unfounded assumptions.

It would perhaps be more fruitful to further study the issue, and/or further publicize the results of studies addressing commercial support of CME and any associated bias."

— Sandra J.P. Dennis, Deputy General Counsel for Healthcare, the Biotechnology Industry Organization (BIO).

Confusing the Issue

"Creating a multitier designation of accreditations will add confusion, especially if the next step will be fractional CME credits depending on the designation. Simply ensuring the honest disclosure of support and whether it is unrestricted or not is sufficient for attendees to make up their own minds about the program."

— Jeffrey Uppington, M.B.B.S., member of the California Society of Anesthesiologists, in response to ACCME's proposed "commercial support-free" designation.

For more information or to read more comments, visit accme.org.

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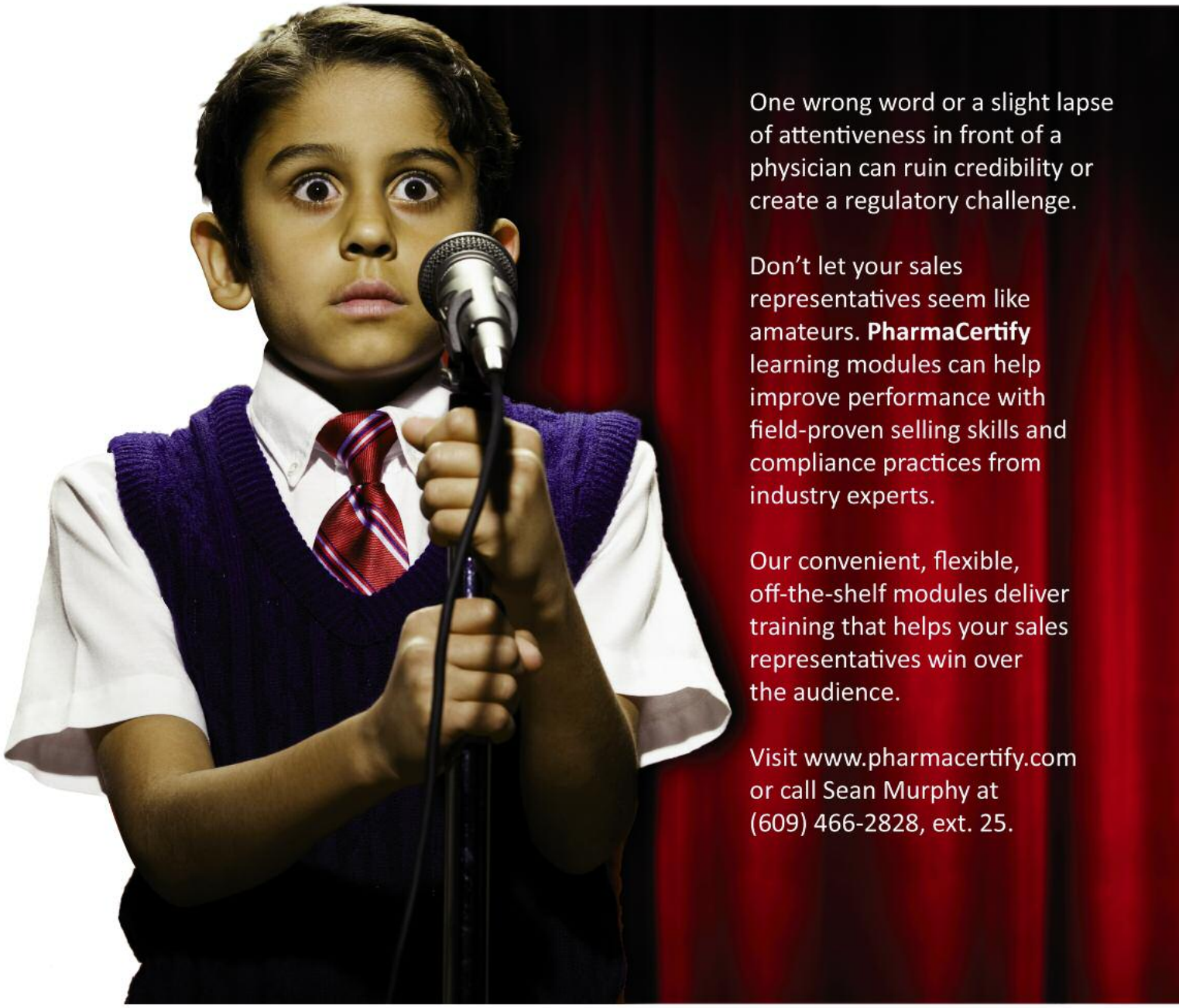

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