ANNUAL REPORT 2012

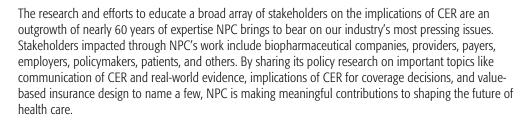


The National Pharmaceutical Council (NPC) is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation's major research-based pharmaceutical companies, NPC focuses on research development, information dissemination, education and promotion of the critical issues of evidence, innovation and the value of medicines for patients. NPC actively participates with a variety of health care stakeholders to demonstrate and communicate the value of biopharmaceuticals and vaccines through practical, evidence-based applications and tools.

Chairman's Message

The National Pharmaceutical Council (NPC) continues to play a critical role in the rapidly changing external environment, and is poised to be an important voice in the years ahead. Through policy research and scientific analysis, NPC remains uniquely positioned to study the contribution of innovative medicines to patient health and wellness, as well as inform policymaker and payer discussions regarding the broader role of medicines in the US health care system.

With the establishment of a research agenda and initial grant announcements, the Patient-Centered Outcomes Research Institute (PCORI) began to crystallize its vision for comparative effectiveness research (CER) this year. As the discussion continues to evolve, NPC has taken the crucial step of projecting future paths CER might take, considering both its promise and unintended or unforeseen consequences. It has become clear that, while CER may have the potential to improve outcomes and contain costs, every stakeholder must be vigilant in shaping the landscape going forward. NPC's work has already helped inform the public debate, even in these early stages.



NPC recognizes the importance of ensuring that research is designed, conducted and analyzed appropriately so that it can be used to inform health care decision-making. As new discussions emerge around the ways CER should be used and the value of real-world evidence, NPC is leading the way in defining and adopting best practices in evidence evaluation and decision-making. In 2012, a number of NPC programs addressed the need for payers to take a more sophisticated approach to pricing and reimbursement decisions as treatment becomes less uniform and more tailored toward each individual. Defining the optimal role and value of pharmaceuticals in evolving payment and delivery models will be an important focus of NPC's strategy moving forward.

NPC's leadership is bringing together leading research-based biopharmaceutical companies and engaging them with other partners, helping advance the dialogue to everyone's benefit. In November I passed the gavel to incoming Chair John Gargiulo of Daiichi Sankyo, Inc. I did so knowing that NPC will continue to move the health care dialogue forward with increased focus on balancing the needs of individual patients and the population at large; the value of pharmaceuticals in achieving optimal health outcomes; and the use of real-world evidence that ultimately supports the highest quality patient care.

Rich Fante President US

& Regional VP Americas

AstraZeneca

Chairman, NPC 2012 Board of Directors



President's Message



Health policy took center stage in the political dialogue for much of 2012. Although the US Supreme Court's decision to uphold the Patient Protection and Affordable Care Act addressed key issues and many elements of the law have gone into effect, other questions remain unanswered. States and agencies struggled to interpret the law and both political parties tried to articulate policies that would enhance patient care and improve outcomes. Stakeholders continued to grapple with these issues and debated how to implement the law in a manner that would maximize the benefits for patients.

Within that context, the National Pharmaceutical Council's work over the last year has focused on informing the discussion with sound policy research on the critical issues of evidence, the value of medicine for patients, and innovation. NPC provided research to policymakers, patients, health care providers and payers that helped sharpen the focus of the discussion and address issues largely overlooked within the dynamics of the evolving health care landscape. By serving this role, NPC is ensuring that opportunities to improve patient care and outcomes do not go unexplored as the comparative effectiveness research (CER) environment takes shape.

In 2012, NPC sponsored and conducted research that resulted in more than one dozen research publications, both peer-reviewed and self-published. The publications examined the most pressing topics in CER, individual treatment effects, and the optimal role and value of pharmaceuticals in evolving payment and delivery models. This research was widely circulated to help shape the broader conversation around the role evidence should play in health care decision-making.

NPC further enhanced its research portfolio with the addition of five research grants awarded as a result of a new request for proposal process initiated in mid-2011. In the fall of 2012, NPC and the George Washington University School of Public Health and Health Services announced a CER fellowship program dedicated to specifically addressing the policy implications of CER.

By addressing key constituencies at a variety of high-profile scientific meetings and conferences in 2012, NPC staff members and our research partners accomplished the key objectives of sharing important research findings and highlighting the organization's work. We continued to leverage a variety of communications tools, including social media, to disseminate research findings and connect with health care stakeholders.

Over the last year, NPC concentrated on developing new partnerships and building alliances with other organizations to advance health care reform. Taking the lead on behalf of the research-based biopharmaceutical industry, NPC facilitated collaboration among stakeholders on key research issues. Policy and research-based alliance-building remains an important focus of our work as we operate from our new Pennsylvania Avenue headquarters in downtown Washington, DC.

As we continue our work on these important issues, we remain committed to growing our membership. In 2012 we were proud to welcome Genentech, Inc., Allergan, Inc., and Amgen as new members of NPC.

Our Board of Directors plays an invaluable role in shaping NPC's research and program agenda, and we greatly appreciate the Board's dedication and involvement in the organization. Special thanks go to outgoing Chairman Rich Fante, under whose leadership NPC became a more effective voice in educating key stakeholders about the real-world implications of CER in improving health outcomes.

NPC is dedicated to providing trusted and credible resources to help stakeholders navigate the complicated health care landscape. In the coming year, we look forward to continuing to inform health policy in a way that ultimately enhances value and achieves better health outcomes for both individual patients and the population as a whole.

Dan Leonard

President, National Pharmaceutical Council

Issues Overview

At the start of 2012, the health care landscape was clouded in uncertainty. It was unclear whether the US Supreme Court would uphold the Affordable Care Act (ACA); if Congress would defund research entities such as the Agency for Healthcare Research and Quality (AHRQ); and what impact the Patient-Centered Outcomes Research Institute's (PCORI) National Priorities for Research would have on research and the pharmaceutical industry. There was, however, clarity around one issue: regardless of the answers to those questions, patients, payers, providers and other health care stakeholders would continue to conduct and use comparative effectiveness research (CER) to make important treatment, coverage and policy decisions.

To ensure the development of high quality CER, its utility and its proper communication, NPC's research, public commentary, and outreach focused on moving the conversation forward in several key areas:

- Recognizing that individual treatment effects must be considered in the design and conduct of CER;
- Appreciating the role that pharmaceuticals can play in a value-based environment like an accountable care organization;
- Providing health care stakeholders with tools to evaluate and translate evidence for use in decision-making;
- Understanding the challenges and opportunities with selecting appropriate research methods, soliciting stakeholder feedback, and engaging methodological experts; and,
- Considering how to create a broader opportunity for the communication, dissemination and exchange of CER.

By year's end, the ACA was upheld; AHRQ's funding remained intact; and PCORI's priorities were becoming more specific, addressing many of the industry concerns raised via NPC's research. New



challenges and questions are arising as CER gradually transitions from a concept to a reality embedded in daily practice. NPC will continue to engage and collaborate with other stakeholders to ensure that CER realizes its full potential, and to call attention to issues that could impact patient health outcomes.



NPC Research

NPC's research helps to inform many critical health care policy debates and supports the organization's overall goal of achieving the best patient outcomes in the most efficient way possible. NPC's research activities are intended to strengthen public understanding of pharmaceutical innovation and of how sound science and evidence can facilitate better decision-making among health care stakeholders.

Major research published and disseminated in 2012 included:

Making Informed Decisions: Assessing the Strengths and Weaknesses of Study Designs and Analytic Methods for Comparative Effectiveness Research provides brief descriptions of both experimental and non-experimental study designs and methods as part of a larger effort to develop a systematic approach to determining which methods are best able to address given CER study questions. NPC members and external stakeholders are using this as a resource and training tool for their constituents.

The State of Comparative Effectiveness Research and the Environment for Health Care **Decision-Making**, NPC's second annual survey of key health care stakeholders, finds that stakeholders clearly recognize the importance of CER and its promise for the future. Results indicate that, while tempered optimism exists about progress in efforts to provide or improve the tools necessary for CER, significant effects of CER are yet to be realized.

Pharmaceutical Technology Assessment: Perspectives From Payers, published in the *Journal of Managed Care Pharmacy*, explains that the processes and evidence used in making pharmaceutical coverage decisions vary substantially among US health plan payers. These variations in the pharmaceutical technology assessment process could affect reimbursement and patient access, and potentially impact health outcomes across health plans.

NPC Chief Science Officer Dr. Robert Dubois authored



A Translation Table for Patient-Centered **Comparative Effectiveness Research-Guidance** to Improve the Value of Research for Clinical and Health Policy Decision-Making, published in the Journal of Comparative Effectiveness Research, explores the challenges and opportunities with selecting appropriate research methods, soliciting stakeholder feedback, and engaging methodological experts. This collaborative project was conducted by NPC, the Center for Medical Technology Policy, and Outcome, a Quintiles Company.

Looking at CER From the Pharmaceutical Industry Perspective, a supplement to the May 2012 *Journal of* Managed Care Pharmacy, includes an article by NPC Chief Science Officer Dr. Robert Dubois taking a closer look at CER and its potential implications for the pharmaceutical industry. The special supplement was based on presentations made at a satellite symposium at the Academy of Managed Care Pharmacy 2011 Educational Conference.

Journal of

Comparative

Effectiveness



The Role of Pharmaceuticals in Value-Based Healthcare: A Framework for Success showcases the development of a conceptual framework for considering the role of pharmaceuticals in a value-based environment such as an accountable care organization. Developed by NPC, the American Medical Group Association, the Premier health care alliance and seven provider organizations as part of the Working Group on Optimizing Medication Therapy in Value-Based Healthcare, the framework includes a condition-specific grid that lays out the cost and quality impact pharmaceuticals may have on each condition. The framework was published as a web exclusive in the American Journal of Managed Care and presented during a webinar on October 16. Members of the Working Group and Dartmouth Institute also shared the framework at the Accountable Care Organization (ACO) Congress at the end of October.

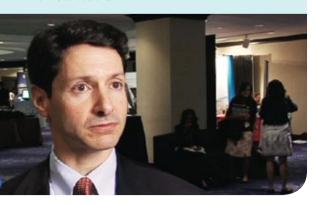
Imputing Productivity Gains From Clinical Trials, conducted

by NPC and Tufts Medical Center, demonstrates a novel approach to measure productivity, using depression and arthritis as case studies. Published in the *Journal of Occupational and Environmental Medicine*, the study finds that therapies to treat depression yield a 0.9 percent to 2.2 percent improvement in employee productivity, and taking medicine to treat arthritis or other musculoskeletal pains is associated with productivity gains of up to 0.5 percent. The study results can be valuable to employers as they make decisions about health care and pharmaceutical benefits.

Principles for Planning and Conducting Comparative Effectiveness Research examines existing health technology assessment principles and sets out 13 best practices that could help to ensure more consistency in how CER is planned and conducted. Numerous CER experts and health care stakeholders were engaged in developing the best practice principles, which were published in the *Journal of Comparative Effectiveness Research*.

Current Challenges in Comparative Effectiveness Research, a cluster of articles sponsored by NPC that were published in the October 2012 issue of *Health Affairs* and addressed at a

Dr. Peter Neumann, professor and director, Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, explained NPC-sponsored research examining guiding principles for the conduct of CER.



related briefing on October 11, raised awareness of the uneven playing field in the health communications landscape, including the pharmaceutical industry's challenge to correct the spread of erroneous or misleading information and supply the quality research that stakeholders are seeking. The articles in this cluster-including one authored by representatives from NPC member companies—reacted to a hypothetical case study of CER involving a fictional migraine drug. Questions raised included how those research findings could be disseminated and communicated by various health care stakeholders, how patient involvement in the study could have improved the usefulness of the results, and whether there are barriers to the uptake of CER in clinical practice.



The Good, the Bad and the Different: Deciphering Heterogeneity for Managed Care Pharmacy and Medical Directors, a

project led by the University of Arizona College of Pharmacy, equips managed care organization pharmacy and medical directors with the tools to critically evaluate CER and promote appropriate interpretation and consideration of individual treatment benefits in the decision-making process. The research materials were presented during a satellite symposium at the Academy of Managed Care Pharmacy's Educational Conference in October.

As part of a new "request for proposal" process launched in 2011, NPC funded additional research projects in 2012 focusing on individual treatment effects, or heterogeneity, and the impact of CER on medical payment policies. In 2012, NPC also undertook research to consider the effects that specialty medications have had on health outcomes and overall health costs; to develop and test a framework for determining which factors influence

Dr. Eleanor Perfetto, senior director, evidence based strategies, Pfizer, Inc., spoke at an October briefing focusing on a cluster of articles in Health Affairs addressing the uneven playing field in the health communications landscape.



individual variability in response to treatment; to examine the role pharmaceuticals could play in best managing high-cost patients; and to better understand how observational studies are considered in clinical guidelines, among other projects.

Some of this research is targeted for publication in 2013, while other projects are longer term.

In addition to NPC's research portfolio, NPC Chief Science Officer Dr. Robert Dubois serves as an associate editor for the *Journal of Comparative Effectiveness Research*, a peer-reviewed, bimonthly publication launched in January 2012. Dr. Dubois contributes a regular column, "From Methods to Policy," focusing on how CER impacts health care and the challenges related to conducting, translating and disseminating CER. In addition, in late 2012 Dr. Dubois accepted an invitation to serve on the editorial advisory panel for the policy journal *Health Affairs*.

In the fall of 2012, NPC, in conjunction with The George Washington University School of Public Health and Health Services (SPHHS), announced a two-year post-doctoral Fellowship in the Policy Impact of Comparative

Copies of NPC-sponsored research are available in the NPC online research library:

www.npcnow.org/research

Effectiveness Research, with the goal of combining training in CER and CER programs with an increased understanding of related health care policy. Although there are many academic programs that train researchers in how to conduct and apply CER, and there are many programs that focus on understanding and developing health care policy, there are very few programs that bring these two areas together. This new Fellowship aims to bridge that gap and to raise awareness and understanding of the policy implications of CER. The Fellow will be an employee of NPC and will have an adjunct faculty appointment in the SPHHS Department of Health Policy.

Programs, Partnerships, and Other Outreach

NPC recognizes the importance not only of researching the key health care topics of the day, but also of widely sharing important findings and insights to inform and advance the nation's health care policy conversation. Through its professional programming, NPC provides a pharmaceutical industry perspective and expertise to the broader discussion. NPC sponsors forums, webinars and symposia where a broad range of stakeholders—including providers, patients, payers, policymakers, and others—can explore and address crucial questions facing the health care system. By partnering and collaborating with other organizations, building alliances to fund and share research, offering comments on proposed research guidelines, and hosting educational events, NPC is further advancing the public dialogue on important health issues.

NPC programs, partnerships, and other outreach efforts over the last year focused on issues relating to:

- Informing and shaping the debate on individual treatment effects, or heterogeneity, and the role of pharmaceuticals in achieving the best patient outcomes;
- Defining the optimal role and value of pharmaceuticals in evolving payment and delivery models; and
- Demonstrating real-world evidence as a critical source of evidence in measuring value.

Communicating CER Findings

Dr. Robert Temple, deputy center director for clinical science, Center for Drug Evaluation and Research, Food and Drug Administration, addressed the NPC conference on communicating CER findings.



NPC initiated a public discussion around the way CER information is shared by hosting a conference, **Asymmetry in the Ability to Communicate CER Findings: Ethics and Issues for Informed Decision-Making** (February 9). As more CER studies are conducted and a growing body of data is released, stakeholders will need to distinguish high-quality findings from those that may be weak or misleading. In the current environment, strict regulations prevent industry experts from speaking out to correct inaccuracies that could influence health care decision-making. Keynote speaker Dr. Robert Temple, deputy center director for clinical science, Center for Drug Evaluation and Research, Food and Drug Administration, sparked more conversation by noting that biopharmaceutical companies are not completely constrained as long as they avoid any promotional behavior.

NPC President Dan Leonard examined current challenges in CER at an October Health Affairs briefing.



NPC President Dan Leonard and Chief Science Officer Dr. Robert Dubois built on this growing discussion during a *Health Affairs* briefing, **Current Challenges in Comparative Effectiveness Research** (October 11). They examined legal issues on promotion and communication of CER, patients' concerns, the use of research by payers and clinicians, and ways to move CER forward. The briefing featured a variety of stakeholder perspectives, and all of the issues addressed were explored in-depth in the October issue of *Health Affairs*, which received funding support from NPC.

Considering Individual Treatment Effects

CER can shed light on which treatments are the most promising, but those insights can be mistaken as a recipe for optimal outcomes in every patient. NPC, the National Health Council, and WellPoint sponsored **The Myth of Average: Why Individual Patient Differences Matter** (November 30) to explore the issue of individual treatment effects, or heterogeneity, and the extent to which differences among patients exist and should be considered in developing treatment decisions, practice guidelines, and/or coverage and reimbursement policies. Speakers broke down the myth of the "average" patient and analyzed how failure to individualize care may contribute to poor clinical outcomes and health disparities. Patient-Centered Outcomes Research Institute (PCORI) Executive Director Dr. Joe Selby and Centers for

Medicare and Medicaid Services Chief Medical Officer Dr. Patrick Conway were the keynote speakers.

An NPC-sponsored satellite symposium held in conjunction with the Academy of Managed Care Pharmacy (AMCP) Educational Conference also highlighted these issues. Pharmacy and medical directors, clinical support pharmacists, and other clinicians received CE/CME credits for their participation in **The Good, the**

Bad, and the Different: Deciphering Heterogeneity (October 3). The symposium explored the clinical importance of individual treatment effects and ways to make better use of evidence to improve health outcomes.

A preconference symposium sponsored by NPC on "Individual Treatment Effects: From Research to Action," at the **International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 17th Annual International Meeting** (June 3) also explored how CER can incorporate and consider the different reactions patients may have to the same treatment.

PCORI Executive Director Dr. Joe Selby was a keynote speaker at NPC's November conference, "The Myth of Average: Why Individual Patient Differences Matter."



Reviewing CER Methods

Although observational studies offer an important way to obtain real-world evidence on how well various treatments work, many payers and other stakeholders have little experience assessing the quality of this research method. In 2012, several NPC programs highlighted the significant role real-world studies can play in informing clinical practice.

The strength of observational studies was among the topics highlighted during the **ISPOR 17th Annual International Meeting** (June 2-6). NPC played a prominent role throughout this event, which was attended by more than 2,000 health outcomes researchers and academics. NPC research was showcased at several presentations, including sessions on "Lessons Learned in the Translation and Dissemination of Comparative Effectiveness Research"; "GRACE Checklist: Rating the Strength of Evidence for Observational Studies of Comparative Effectiveness"; and "Clarity, Consistency, and Transparency in Decision-Making: Testing a Novel P&T Framework for Assessing Evidence." NPC's exhibit booth attracted hundreds of visitors, providing additional opportunities to disseminate the latest research.

NPC Director of Comparative Effectiveness Research Dr. Jennifer Graff highlighted the challenges in determining individual treatment effects during NPC's "Myth of Average" conference.



Comparative Effectiveness: A Real-World User's Guide (March 14-15), a two-day meeting hosted by NPC and the Drug Information Association, highlighted the changing nature of evidence standards within the marketplace; specifically, the continued push for increased levels of evidence of comparative effectiveness applied within health technology assessments (HTAs). The meeting focused on the application of CER and HTAs within drug development and research planning and provided participants with takeaways to apply within day-to-day drug development and marketing activities.

Putting CER Into Practice

Disseminating information on the results of CER studies to health care providers and patients is a critical task. A webinar on **CER and the Environment for Health Care Decision-Making: Findings From the Annual Survey of Health Care Stakeholders** (March 27) featured NPC President Dan Leonard and Dr. Claudia Schur, director and vice president, Center for Health Research and Policy, Social & Scientific Systems, presenting the results of NPC's second annual survey of key health care stakeholders. The survey found that stakeholders recognize the importance of CER and its promise for the future, but do not believe it has had a significant impact on health care decisions to date.

NPC was a sponsor and Chief Science Officer Dr. Robert Dubois served as a co-chair for the **Fourth National Comparative Effectiveness Summit** (November 5-6) on the role of CER in health system change and health reform. Dr. Dubois presented on "CER at the Point of Decision-Making—Introduction and a Framework for Understanding When CER Adoption Occurs," and "Communicating CER Information: The Dueling Goals of Public Health and Commercial Speech," and moderated faculty question and answer sessions on both topics.

Additional Outreach

NPC presentations and speaking engagements at other significant industry meetings and conferences helped assure that key issues remained at the forefront of discussions among thought leaders throughout 2012. The following were among the presentations that brought results of NPC-sponsored research to new audiences and stakeholders:

NPC Director of Health Services Research Kimberly Westrich addressed the Food and Drug Law Institute's Advertising and Promotion conference.



- Tufts Center for the Study of Drug Development Forum on the Impact of Comparative Effectiveness Research on Biopharmaceutical Innovation and Patient Access (January)
- Harvard Post-Approval Summit (May)
- AcademyHealth Annual Research Meeting (June)
- Drug Information Association Annual Meeting (June)
- Food and Drug Law Institute's Advertising and Promotion Conference (October)
- National Managed Care Payer Roundtable (October)
- The Third National Accountable Care Organization Congress (October).

NPC partners with other associations, organizations and coalitions to raise awareness and bring key issues to the attention of even broader audiences. NPC was a sponsor for the Integrated Benefits Institute and National Business Coalition on Health's Health and Productivity Forum (February), the Health Industry Forum event, "Generating Evidence to Advance Molecular

Diagnostics" (July), and a Friends of Cancer Research Forum on Co-Development of Targeted Therapies and Companion Diagnostics (September).

A major partnership with AMCP and ISPOR is focusing on **Advancing the Appropriate Use of Comparative Evidence to Improve Patient Health Outcomes**, bringing together researchers, payers, and industry to enhance the understanding of the requirements for high-quality CER and enable greater uniformity and transparency in the evaluation and use of well-designed CER for coverage and health care decision-making. This collaborative AMCP/ISPOR/NPC project will continue into 2013.

A Leadership Roundtable co-hosted by Friends of Cancer Research (FOCR) and NPC featured Dr. Ellen Sigal, founder and chairperson, FOCR, Dan Leonard, president, NPC, and Dr. Janet Woodcock, director, Center for Drug Evaluation and Research, Food and Drug Administration.



Chief Science Officer Dr. Robert Dubois was among the NPC experts quoted in national media outlets in 2012.



Other major partnerships in 2012 included collaboration with the Center for Medical Technology Policy focused on methods and standardization and with the Institute for Clinical and Economic Review focused on real-world application of CER. Partnerships with the National Business Coalition on Health, the National Consumers League, the Pharmacy Quality Alliance, and several other groups all focused on the value of pharmaceuticals in evolving payment and delivery models.

NPC also reaches health care stakeholders via traditional and online media outlets, e-newsletters, and social media. In 2012, reporters continued to seek out NPC's

experts and research as resources for quality reporting on the changing CER landscape. *The Pink Sheet, The Economist, Inside Health Policy, Chain Drug Review, Politico Pulse, Bloomberg Government, CQ HealthBeat* and *Drug Industry Daily*, among others, quoted NPC's representatives or cited NPC-sponsored research. NPC continued to provide its own free, daily source on CER news and information with the *CER Daily Newsfeed*. In addition, NPC maintained an active presence on Facebook, LinkedIn and Twitter (@npcnow), providing timely information and extending its reach to new audiences.

Patient perspectives were the focus of remarks by National Health Council President Myrl Weinberg, FASAE, CAE, at NPC's "Myth of Average" event.



NPC Members

NPC's membership is composed of the top research-based biopharmaceutical companies in the world. A leading voice for the industry, NPC complements other life science associations by providing in-depth research, analysis and education on emerging issues.

NPC provides its members with opportunities to:

- Engage US health policymakers through the delivery of credible, authoritative research
- Participate directly in setting the organization's research agenda
- Collaborate with leading third-party scientific and policy experts from across key health care sectors
- Leverage credibility via NPC relationships with multiple stakeholders
- Network with leaders and colleagues across the biopharmaceutical industry
- Participate in NPC technical and scientific work groups and research discussions with industry peers, including members-only symposia and town hall meetings
- Access NPC educational resources, including practical tools, analytical papers and an expanded video library.

NPC Members 2012







































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Additional NPC resources available online include:

Daily electronic CER Update



www.npcnow.org

Website includes a research and publications library



Monthly electronic newsletter





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