

ANTICOAGULATION FORUM

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INSIDE THIS ISSUE:

NCBAP Update	page 2
NATT Update	page 3
Board of Directors.....	page 4
Updates from Literature.....	page 6

President's Column

This issue of our newsletter includes a letter from the AC Forum Board of Directors to Dr. Lawrence Lesko, Director, Office of Clinical Pharmacology at the FDA. During a plenary session at our conference in Chicago, Dr. Lesko described the rationale for the FDA's plan to add information about genotype testing to the warfarin package insert. The Board's letter outlines our concerns about how such information would be added to the warfarin label. I am pleased to report that Dr. Lesko was kind enough to join us for a conference call in which we had the opportunity to voice these concerns and to hear the perspective of the FDA on this issue. Dr. Lesko has outlined this perspective in a reply to our letter - also included with this newsletter.

The Board has sent the FDA some suggested language that we feel would most accurately portray the facts about genotype testing. Although he cannot assure us that any of the language we have proposed will be included in the final change to the package insert, I am confident that Dr. Lesko and his colleagues at the FDA will consider our concerns about liability for clinicians and the paucity of clinical outcomes data as they make their final decisions on this important matter.

I hope that all of you who were able to attend the 9th National Conference on Anticoagulant Therapy in Chicago enjoyed all aspects of the meeting as much as I did. The educational sessions were packed with useful information and the opportunities to "network" or catch up with old friends were numerous. For those of you who were not able to make it to Chicago, I hope you'll strongly consider joining us in San Diego May 7-9 of 2009. ■

We are pleased to announce the launch of "Anticoagulation Updates from the Literature", see page 4 to learn more.

Letter to FDA from AC Forum Board of Directors

June 15, 2007

Lawrence J. Lesko, PhD, FCP
Director, Office of Clinical Pharmacology and Biopharmaceutics
Center for Drug Evaluation and Research
Food and Drug Administration

Dear Dr. Lesko,
The Board of Directors of the Anticoagulation Forum would like to thank you for your informative presentation at our 9th National Conference in Chicago in May 2007. Like you, we are enthusiastic about the potential future role of pharmacogenomics in the management of oral anticoagulant therapy. It is clear that polymorphisms of the CYP2C9 and VKORC1 genes both have an impact on warfarin dosing requirements, and preliminary evidence suggests that initial warfarin doses may be estimated more effectively by considering CYP2C9 and VKORC1 genotype as well as numerous other contributing factors. However, there is no indication yet that the addition of genotyping will improve clinical outcomes. In our view, evidence of

continued on page 4

Response Letter from the FDA

June 25, 2007

Dear Dr. Garcia,

On behalf of the warfarin working group in the FDA's Center for Drug Evaluation and Research (CDER), I want to express my thanks for the expert comments and insights that you and the Board of Directors provided us following my presentation at the 9th National Conference of the Anticoagulation Forum in Chicago in May 2007. We have reviewed these comments seriously and appreciate the invitation to respond to them with this letter.

continued on page 5

NCBAP Update

The NCBAP Board of Directors met on May 3, 2007 at the Anticoagulation Forum meeting in Chicago. Committees are currently working on a variety of activities including exam item development, revisions to the candidate handbook, and the use of information technology solutions to streamline the application and certification process. We would like to introduce our newest Board member, Diane Wirth, ANP-BC, CACP. Diane is the Manager of Clinical Operations at Emory Healthcare in Atlanta, GA. Diane's experience will be an asset to the NCBAP board and we look forward to working with her.

May 3rd also marked the date for the Chicago certification exam. An exam was also held in Boston in March. Future exams for this calendar year are scheduled for November 10, 2007 in Boston, MA and December 2, 2007 in Las Vegas, NV. The December exam will be offered in conjunction with the ASHP Mid-Year Meeting. Tentative plans have been made for an exam in Albuquerque, NM in January or February of 2008. Please note that applications are due 2 months prior to the date of the exam.

All current CACPs who received their certification prior to December 31, 2002 must renew their certification prior to the end of this calendar year (December 2007). Those needing to recertify may do so online or may opt to sit for the November 10th or December 2nd exams. Typically, 2 to 3 online exam dates are offered each month, and dates may be added upon request. To date, 8 individuals have recertified online, and the feedback regarding the online process has been positive. Visit our website for more details regarding the online recertification process.

Clinicians interested in seeking certification in anticoagulation management can find information and download the CACP Candidate Handbook and Application from our website. Visit: www.ncbap.org. Specific questions can be directed to info@ncbap.org

Congratulations to our newest CACPs and those who have recently recertified at the March, May, and online exams:

Lilian Alade..... Clarksville, MD
Elise Arambages New York, NY
Allen Arthur Reno, NV
Nathan Ash Evansville, IN
Stephanie Barud Edmond, OK
Charlene Bechen Banks, OR
Jennifer Bird..... Yukon, OK
Jennifer Bolding Little Rock, AR
Bobbie Jo Bradley..... Billings, MT

Debra Brasier Cary, IL
Wendy Cantrell Las Vegas, NV
Dawn Chandler..... Indianapolis, IN
Janet Delaney Bradenton, FL
Ditina Desai Washington, DC
Susan Dick Vicksburg, MI
Chris DiPaola..... Sunapee, NH
Ashley Dollar Columbia, SC
Mohammed Elfaour..... Powell, OH
Amanda Ferstl..... Little Rock, AR
Jennifer Gemell Rye, CO
Gerard Greskovic..... Clarks Summit, PA
Denelle Hall St. Petersburg, FL
Josephine Hao Sammamish, WA
Sandra Hart Northboro, MA
Karen Hocking..... Traverse City, MI
Jane Holmes Butler, PA
Janice Hufnagle Dover, PA
Melissa Hull..... Federal Way, WA
Nancy Jordan Liberty Lake, WA
Laura Keefer Lutherville, MD
Sei Keng Koh..... Singapore
Gloria Koth Appleton, WI
Tamara Kozlowski Elkridge, MD
Terri Lam..... Monterey Park, CA
Laura Lehman Elliot City, MD
Michelle Mastropietro Wolcott, CT
Michele Meredith San Diego, CA
Lisa Moherman Morgantown, WV
Brian Murray..... Fletcher, OK
Carol Neel..... Louisville, KY
Jessica O' Donnell Tampa, FL
Susan O'Neill Staten Island, NY
Katherine Phillips Newton, MA
Leslie Pittman Spring Hill, TN
Mary Rogers Stow, MA
Maria Say..... Glen, AZ
Amory Schwier Lawrenceberg, IN
Rachel Seaman Virginia Beach, VA
Marjorie Showlater Sarasota, FL
Brooke Sipe..... Ft. Wayne, IN
Patrick Spenik New Kensington, PA
Liqin Audrey Toh Singapore
Mei Tse..... Los Angeles, CA
Lisa Vaughn Wenatchee, WA
Kathryn Vokaty..... Durham, NM
Jodiann Wagner Spokane, WA
Yee May Wong Singapore
Mei Ling Nancy Yong Singapore

From the President

In April 2007 I became NATT's president and am now trying to fill the shoes of Mark Jablonski, NATT's first president and a founding member. It is an honor to work with an outstanding volunteer board of directors, a Medical and Scientific Advisory Board composed of internationally known physicians and health professionals and the many volunteers who support the work of NATT through their committee activities. Every day NATT takes another step to fulfilling its role as the country's voice for individuals and families affected by blood clots and clotting disorders.

During the first few months of my 3 year term as President, we have already undertaken a number of new activities. Under the leadership of our new Executive Director, Alan Brownstein, we opened a new headquarters in Tarrytown, NY (520 White Plains Rd., Suite 500, Tarrytown, NY 10591; tel. 914-4677808; fax 914-467-7801). In June the Board held a strategic planning meeting in Washington, DC to map out future efforts in fundraising, education, communications and outreach. Our Income Development Committee has become a focus, as we realize the importance of building a solid foundation for the future of NATT. We are also looking at strategic alliances with groups such as the AC Forum to leverage our resources and expand our ability to get the message on thrombosis and thrombophilia out to the public. We continue to provide our patient education seminars, having recently completed our 5th seminar of the year. We are already looking towards our next in Salt Lake City, UT on November 10, 2007.

Our communications committee recently published the NATT bi-annual newsletter on "Children and Blood Clots" and intends to produce even more newsletters next year in response to increased demand. We are now sending our newsletter to every member of Congress, in addition to our expanding database of interested consumers and health professionals. We were delighted to see that many of you signed up at the AC Forum meeting to be on our mailing list, to receive brochures and/or co-host a seminar. Your names are being added to our database and we will follow-up with you as soon as possible. If you know other colleagues or patients who would like to sign up, please write us at nattinfo@yahoo.com.

The increased level of activity this year tells me I can look forward to an exciting and busy term of office. We look forward to continuing to work with the AC Forum and other partners in bringing the message about blood clots to the millions of Americans affected one way or another by thrombosis and thrombophilia.

Sincerely,
Randolph B. Fenninger
President, NATT

Chicago Conference Huge Success

Thank you to all attendees and presenters at our 9th National Conference on Anticoagulant Therapy this past May in Chicago. It was the most well attended conference to date with 800 participants. Attendees had the opportunity to hear from over 20 speakers, examine more than 40 poster presentations of original research, and mingle with colleagues. Additionally, Chicago provided a fun-filled venue in which to relax at the end of the day.

Some of the highlights included Lynn Oertel and Ann Wittkowsky's heartfelt presentation thanking Dr. Jack Ansell for his 16 years of service to the AC Forum and Dr. David Garcia's official introduction as president of the AC Forum. The Saturday afternoon session focusing on improving patient quality of life was a new addition to the conference, and more than 60 people took the NCBAP exam. Proceedings of the meeting will be published this winter in the *Journal of Thrombosis and Thrombolysis*.

Finally, it's not too soon to begin thinking about the next conference. The 10th National Conference will be held in San Diego on May 7-9, 2009 at the Manchester Grand Hyatt. Save the date!

For more information on the
Anticoagulation Forum, please visit our
website at: www.acforum.org



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****NEW** Anticoagulation Updates from the Literature**

Anticoagulation Updates from the Literature is the newest initiative from the AC Forum. It is a publication designed to provide a summary of some of the most recent research going on in the field, published in leading journals. Following the summary, there is a brief clinical implications statement, designed to let you know how the research will affect your practice.

The first issue of Anticoagulation Updates from the Literature was distributed to all attendees at the AC Forum's recent conference in Chicago. We are reprinting the issue here in the newsletter so that all members can read it. Anticoagulation Updates will be issued multiple times per year in electronic form. If you are interested in receiving this via email, please sign up at our website, www.acforum.org. ■

Anticoagulation Forum Board of Directors

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continued from page 1

Letter to FDA

improved clinical outcomes that are directly attributable to genetic testing is necessary before genotyping can be embraced as part of routine clinical practice.

Further studies using clinical outcome measures, comparing current dosing strategies to pharmacogenetic dosing, should be conducted to determine the benefits of pharmacogenetic testing. Many of us would be happy to assist in design and implementation of such research. However, in the absence of this evidence, we are concerned that the cost and implementation of genotyping cannot be justified.

We would also like to raise the possibility that gene testing could be harmful. Other logical, well-intended practices (e.g. lidocaine for PVC's post-MI) that have been adopted without direct evidence of improved clinical outcomes have, in some cases, later proved to be detrimental. In the case of genotyping, we are concerned that:

- Practitioners could acquire a false sense of complacency about the need for rigorous monitoring by assuming that genotyping will lead to accurate dosing.
- The wait time for genotyping results may delay the initiation of therapy leading to adverse events.
- Patients who appear (based on gene testing) to be extremely sensitive to warfarin could get systematically underdosed and thus be at higher risk for thrombosis.

None of these possibilities can be excluded without an outcomes-based clinical trial.

For liability reasons, we feel that any mention of genotyping in the warfarin label should reflect the uncertainty about the benefit of this testing. The decision to forego genotyping should not place any liability on the clinician responsible for warfarin management since there is no high-quality, compelling evidence to indicate that a lack of genotyping information is associated with an increased risk of adverse events. This is a critical issue for our membership, the majority of whom are involved in the day-to-day management of oral anticoagulant therapy.

We look forward to an open dialogue with you and the FDA about the emerging clinical science of pharmacogenomics. We are all interested in furthering research in this area of practice and are willing to lend our expertise to ongoing research efforts.

Sincerely,

David A. Garcia, MD

(on behalf of the Anticoagulation Forum Board of Directors) ■

Response Letter from FDA

The mission of the FDA, as described in law, is to promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated drug products in a timely manner. Evaluation of benefits and risks is a dynamic scientific process as more data becomes available over the life cycle of a medical product.

Warfarin is a drug with a narrow therapeutic range and is used for serious indications. There is little question about the evidence of its effectiveness. There are also no alternative approved oral anticoagulation therapies available. We accept the risks of over- and under-anticoagulation when using warfarin because they are reasonable when weighed against its benefits. In weighing benefits and risks, we consider the circumstances of its use and ways to minimize those risks.

In our view, evidence of a greater risk of not achieving a stable INR as quickly as possible during the induction period, and an increased risk of over- and under-anticoagulation shortly after commencing warfarin therapy, attributable to not considering pharmacogenetics is substantial. At the meeting of the Clinical Pharmacology Subcommittee (CPSC) of the Advisory Committee for Pharmaceutical Sciences in November 2005, the evidence supporting the addition of pharmacogenetic information to the warfarin label was extensively discussed. The CPSC voted unanimously that sufficient mechanistic and clinical evidence exists to support lower doses for patients with certain genetic variations in CYP2C9 and/or VKORC1. The Committee also agreed that genotyping patients prior to, or shortly after, starting warfarin could improve achievement of stable INR and potentially reduce the rate of early bleeding complications. The CPSC voted 8-2 recommending that FDA update the label with information on CYP2C9 and VKORC1 testing. The CPSC also believed that genetic testing should not be mandatory. Please see the following for more information:

- (http://www.fda.gov/ohrms/dockets/ac/05/slides/2005-4194S1_Slide-Index.htm)
- (<http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4194T1.pdf>)

We acknowledge and account for the uncertainty in adding genetic information to the label in light of the absence of prospective, randomized, controlled trials which look at clinical outcomes. However, we consider INR to be an established “surrogate”, albeit imperfect as many “surrogates” are, for clinical outcomes. In deciding how much data is needed to re-label warfarin, we recognize the value of the following information obtained from numerous carefully

designed retrospective and small prospective studies:

- a strong causal (mechanistic) basis for linking variability in response (INR) with fixed doses based on certain genetic variants in CYP2C9 and VKORC1;
- a clear distinction between cases (patients having 1 or more variant alleles) and controls (patients having no variant alleles) based on time to steady state INR;
- consistent within and across study associations in a variety of racial and ethnic groups in the link between pharmacogenetics and dose requirements;
- consistent association between INR control and the risk of adverse events which also forms the basis for endorsing frequent INR monitoring and anticoagulation services.

We also recognize the trade-offs between reporting and not reporting pharmacogenetics in the warfarin label: having less data and greater uncertainty may introduce unanticipated consequences, while requiring more data and lesser uncertainty may delay communication of an effective way to improve INR control. The potential advantages and disadvantages of using pharmacogenetics in warfarin therapeutics cannot be optimized or minimized respectively, without adequate directions for its use in the label. To help patients and health care providers make informed individual decisions about warfarin dosing, it is necessary to communicate this information in the label in a way that is supported by the scientific and clinical evidence.

We look forward to additional open conversations with the Board of Directors and potential collaborative research with Anticoagulation Forum members to further evaluate the impact of warfarin pharmacogenetics on optimizing dosing, and improving INR control and clinical outcomes.

Sincerely,

Lawrence J. Lesko, Ph.D., F.C.P.
Director, Office of Clinical Pharmacology
Center for Drug Evaluation and Research
Food and Drug Administration



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Meta-analysis: Anticoagulant Prophylaxis to Prevent Symptomatic Venous Thromboembolism in Hospitalized Medical Patients

Francesco Dentali, MD; James D. Douketis, MD; Monica Gianni, MD; Wendy Lim, MD; and Mark A. Crowther, MD, MSc

Summary: The rate at which effective antithrombotic prophylaxis is provided to patients with acute medical illnesses is suboptimal. The explanation for sub optimal provision of prophylaxis is unknown. A potential explanation is the lack of evidence that such prophylaxis reduces clinically relevant endpoints. This systematic review assessed the effect of anticoagulant prophylaxis on clinically important outcomes in hospitalized medical patients. In total, 9 studies enrolling 19,958 patients were included. Patients who received anticoagulant prophylaxis had significant reductions in any PE (relative risk, 0.43 [CI, 0.26 to 0.71]; absolute risk reduction, 0.29%; NNTB, 345) and fatal PE (relative risk, 0.38 [CI, 0.21 to 0.69]; absolute risk reduction, 0.25%; NNTB, 400). This benefit was offset by a nonsignificant

increase in major bleeding (relative risk, 1.32 [CI, 0.73 to 2.37]) and there was no impact on all-cause mortality (relative risk, 0.97 [CI, 0.79 to 1.19]).

Clinical Implications: This study suggests that effective anti-thrombotic prophylaxis reduces the risk of clinically apparent venous thromboembolism in patients admitted with an acute medical illness. Ideally, this observation would be confirmed in a large prospective study however the size of the required study probably makes this impractical.

Annals of Internal Medicine 2007;146(4):278-288 ■

Comparison of Outcomes Among Patients Randomized to Warfarin Therapy According to Anticoagulation Control

White HD, Gruber M, Feyzi J, Kaatz S, Tse H-F, Husted S, Albers GW

Summary: This study is a pooled analysis of the 3,587 patients randomized to warfarin in the SPORTIF III and V trials (Stroke Prevention using an Oral Thrombin Inhibitor in atrial Fibrillation). The relationship between INR control and rates of death, bleeding, MI, or stroke was examined. Quality of anticoagulation control was defined as good (>75% time in the 2-3 range), moderate (60-75%), and poor (<60%). Compared to the good control group, the poor control group had higher rates of annual mortality, 4.20% vs 1.69%, major bleeding, 3.85% vs 1.58%, MI, 1.38% vs 0.62%, and

stroke 2.10% vs 1.07%.

Clinical Implications: Time in the 2-3 INR range is associated with decreased death, major hemorrhage, myocardial infarction, and stroke. Overall, approximately 1/3 of patients enrolled in the SPORTIF trials had INR values in the 2-3 range for more than 75% of the observation time.

Archives of Internal Medicine 2007;167:239-245. ■

The Influence of Patient Adherence on Anticoagulation Control with Warfarin. Results from the International Normalized Ratio Adherence and Genetics (IN-RANGE) Study

Kimmel SE, Chen Z, Price M, Parker CS, Metlay JP et al.

Summary: This study of 136 patients in 3 anticoagulation clinics used an electronic Medication Event Monitoring System over a mean of 32 weeks to record the date and time that the warfarin prescription bottle was opened by each patient. Under-adherence, as evaluated by lack of prescription bottle opening, was significantly associated with under-anticoagulation. Thirty-six percent of patients missed more than 20% of bottle openings, equivalent to 1-2 missed doses per week.

Clinical Implications: Poor adherence to anticoagulant therapy significantly influences the stability of anticoagulant control, and is common even in the anticoagulation clinic where adherence is stressed repeatedly throughout therapy.

Archives of Internal Medicine 2007; 167:229-35. ■

Combined Aspirin-Oral Anticoagulant Therapy Compared to Oral Anticoagulant Therapy Alone Among Patients at Risk for Cardiovascular Disease. A Meta-Analysis of Randomized Trials

Dentali F, Douketis JD, Lim W, Crowther M.

Summary: This meta-analysis evaluated the results of 10 clinical trials in which oral anticoagulant therapy was combined with aspirin and compared to oral anticoagulation alone. The 4,180 patients included were anticoagulated for mechanical heart valves, atrial fibrillation or coronary artery disease. Compared to oral anticoagulation alone, combined therapy was associated with a lower incidence of arterial thromboembolism (OR 0.66) but the benefits were limited to patients with mechanical valve replacement (OR 0.27). Combined

therapy did not benefit patients with atrial fibrillation (OR 0.99) or CAD (OR 0.69). Combined therapy did not influence all cause mortality, but increased the risk of major bleeding (OR 1.43).

Clinical Implications: Combining aspirin with oral anticoagulant therapy appears to benefit only patients with mechanical heart valves, and increases the risk of major bleeding.

Archives of Internal Medicine 2007; 167:117-124. ■

Factor IX Inhibitors as Novel Anticoagulants (Brief Review)

Howard EL, Becker KCD, Rusconi C, Becker RC

Summary: A contemporary review of factor IXa Biology in cell-based coagulation and evolving platform for pharmacologic inhibition. Factor IXa is a pivotal protease in coagulation. It is the only soluble coagulation protein that can diffuse from tissue factor-bearing cells to platelets, wherein complex formation with factor VIIIa leads to thrombin generation. Factor IXa inhibitors range from active site blocked antagonists to RNA aptamers (with complimentary antidotes that target binding exosites).

Clinical Implications: An ability to attenuate thrombin generation both on tissue factor-bearing cells and platelets, coupled with drug regulating systems that employ pharmacologically-inert antidotes, may foster safe and effective management of thrombotic disorders and use in prothrombotic extracorporeal circulatory devices.

Arteriosclerosis, Thrombosis and Vascular Biology 2007;27:722-727 ■

Vitamin K Supplementation Can Improve Stability of Anticoagulation for Patients with Unexplained Variability in Response to Warfarin

Elizabeth Sconce, Peter Avery, Hilary Wynne, Farhad Kamali

Summary: Some studies suggest that patients on warfarin with unexplained, unstable INRs have poor, or fluctuating levels of vitamin K intake, and that even small changes in diet may have large effects on the INR. Seventy unstable warfarin-treated patients were randomly assigned to receive 150 ug daily of oral vitamin K or placebo (double blind) for 6 months. Therapeutic control was measured in each group during the 6 months and compared between groups as well as with the degree of control in the preceding 6 months leading up to randomization. Vitamin K supplementation resulted in a significant reduction in the standard deviation of the INR compared to placebo ($p < 0.001$), and a significant increase in time in therapeutic range (59% to 87% in the treated group; a 28% improvement vs 63% to 78% in the placebo group; a 15% improvement;

$p < 0.01$). Anticoagulant control improved in 33/35 patients receiving vitamin K supplementation and only 24/33 placebo patients. Vitamin K supplementation also resulted in an increase in daily warfarin dose requirements of 16% compared to 1.5% in the placebo group.

Clinical Implications: Patients with unexplained instability of their INR control may benefit from a trial of a small daily dose of oral vitamin K (~150 ug/day). Such therapy may stabilize vitamin K levels of individuals who have poor reserves. One must monitor the INR closely during such an intervention because patients will likely need a boost in their warfarin dose to counter the increase in vitamin K intake.

Blood 2007; 109:2419-2433. ■

High Density Lipoprotein and the Risk of Recurrent Venous Thromboembolism

Eichlinger S, Pechneiniuk NM, Hron G et al.

Summary: The investigators studied 772 patients after a first spontaneous VTE (average f/u 48 months) and recorded the end point of recurrent VTE, which occurred in 100 patients. The relationship between plasma lipoprotein parameters and recurrence was evaluated. Patients with, as compared to those without VTE recurrence had lower levels of apolipoprotein AI (1.12 ± 0.22 versus 1.23 ± 0.27 , $p < 0.001$). There was strong trend for an association between recurrence and low levels of HDL particles and HDL cholesterol.

Clinical Implications: The relationship between venous and arterial thrombosis is recognized for several acquired thrombophilias; however, the interface of traditional risk factors for atherosclerosis, such as low HDL cholesterol and VTE has received less attention. The "link" may relate to HDLs effect on Activated Protein C, endothelial cell nitric oxide synthesis and vascular proinflammatory responses.

Circulation 2007;115:1609-1614. ■

Anticoagulation Forum News

- Sign up to receive our new email publication, Anticoagulation Updates from the Literature. Visit our website, www.acforum.org, to sign up.
- We are in the process of updating the clinic locations on our website. Please take a moment to make sure your clinic is listed correctly. Notify us of any corrections by sending an email to Elizabeth.Goldstein@bmc.org.
- The AC Forum's 10th National Conference on Anticoagulant Therapy will be held on May 7-9, 2009 in San Diego at the Manchester Grand Hyatt. Save the date!

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