pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pCODR EXPERT REVIEW COMMITTEE (pERC)
FINAL RECOMMENDATION

The pan-Canadian Oncology Drug Review (pCODR) was established by Canada's provincial and territorial Ministries of Health (with the exception of Quebec) to assess cancer drug therapies and make recommendations to guide drug-funding decisions. The pCODR process brings consistency and clarity to the cancer drug assessment process by looking at clinical evidence, cost-effectiveness and patient perspectives.

pERC Final Recommendation
Upon consideration of feedback from eligible stakeholders, pERC members considered that criteria for early conversion of an Initial Recommendation to a Final Recommendation were met and reconsideration by pERC was not required.

Drug: Abiraterone Acetate (Zytiga) **Submitted Funding Request:** For asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) patients after failure of androgen deprivation therapy (have not received prior chemotherapy).	
Submitted By: Janssen Inc.	**Manufactured By:** Janssen Inc.
NOC Date: May 28, 2013	**Submission Date:** March 28, 2013
Initial Recommendation: October 3, 2013	**Final Recommendation:** October 22, 2013

pERC RECOMMENDATION

The pCODR Expert Review Committee (pERC) recommends funding abiraterone acetate conditional on the cost effectiveness being improved to an acceptable level. Funding should be for patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) after failure of androgen deprivation therapy (ADT), which generally includes an LHRH agonist or orchiectomy, who have not received prior chemotherapy and who have ECOG performance status 0 or 1. pERC made this recommendation because it was satisfied that abiraterone plus prednisone has a net clinical benefit compared with prednisone alone and aligns with patient values. However, at the submitted price and the range of estimated incremental cost-effectiveness ratios, abiraterone plus prednisone could not be considered cost-effective compared with prednisone alone.

POTENTIAL NEXT STEPS FOR STAKEHOLDERS	**Pricing Arrangements to Improve Cost-Effectiveness** Given that pERC was satisfied that there is a net clinical benefit of abiraterone acetate in patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC), jurisdictions may want to consider pricing arrangements and/or cost structures that would improve the cost-effectiveness of abiraterone acetate to an acceptable level. pERC noted that drug price was the key driver of the incremental cost-effectiveness estimates and the budget impact of abiraterone could be large. Therefore, provinces may want to consider additional measures to limit budget impact such as implementing an approved prescriber list to limit indication creep. **Optimal Sequencing of Abiraterone and Other Therapies Unknown** There is currently no evidence available on the effectiveness of retreatment with abiraterone post-chemotherapy in those patients who progress after receiving abiraterone in the pre-chemotherapy setting or the optimal sequencing of other therapies in mCRPC. Therefore, pERC concluded that the optimal sequencing of abiraterone and other treatments in mCRPC is still unknown and pERC was unable to make an informed recommendation on retreatment with abiraterone in the post-chemotherapy setting. However, pERC recognized that provinces will need to address this issue upon implementation of abiraterone funding in the pre-chemotherapy setting.

SUMMARY OF pERC DELIBERATIONS

pERC noted that prostate cancer is the most common malignancy in Canadian men but that the proportion of patients with metastatic castration-resistant prostate cancer is relatively small. However, pERC also discussed that the proportion of asymptomatic or mildly symptomatic patients who have failed androgen deprivation therapy but not received prior chemotherapy is considerably larger than the proportion of patients who are treated later in the course of disease, following chemotherapy, which is the setting where abiraterone has been used to date. Standard treatment for these asymptomatic or mildly symptomatic patients includes hormonal therapies or active monitoring and observation for disease progression to determine when chemotherapy is indicated. pERC noted that there is a need for new and effective treatment options in this setting and that abiraterone would allow patients to delay chemotherapy and exposure to its associated toxicities.

pERC's Deliberative Framework for drug funding recommendations focuses on four main criteria:	
CLINICAL BENEFIT	**PATIENT-BASED VALUES**
ECONOMIC EVALUATION	**ADOPTION FEASIBILITY**

The pCODR systematic review included one randomized controlled trial, Study COU-AA-302 (Ryan 2013) comparing abiraterone plus prednisone with placebo plus prednisone in asymptomatic or mildly symptomatic patients in the pre-chemotherapy setting. pERC deliberated upon the results of Study COU-AA-302 and concluded that there is a net clinical benefit of abiraterone in this setting, primarily based on quality of life measures that favoured abiraterone plus prednisone compared with prednisone alone. pERC also considered that quality of life would be improved by delaying initiation of chemotherapy. pERC also considered that there were statistically significant improvements in other endpoints such as radiographic progression-free survival, median time to decline in ECOG performance status, median time to opiate use, prostate-specific antigen (PSA) response and median time to PSA progression. pERC discussed that the overall survival benefit of abiraterone was not clear in Study COU-AA-302 but considered that the consistent improvements in other endpoints important to patients were sufficient to conclude there was a clinical benefit. pERC discussed the toxicity profile of abiraterone based on Study COU-AA-302 and concluded that the side effects associated with abiraterone were tolerable. pERC further noted that there is experience with abiraterone in the later stages of mCRPC and these results were consistent with current experience managing abiraterone toxicities.

pERC deliberated on alignment of abiraterone with patient values based on input provided by patient advocacy groups. pERC noted that patients valued access to new effective treatments that would provide relief long enough for other treatment options to emerge, which would also allow patients to delay exposure to the toxicities associated with chemotherapy. pERC noted that Study COU-AA-302 demonstrated significant improvements in outcomes important to patients such as quality of life and delaying time to opiate use, which aligns with patient values. In addition, input provided by patient advocacy groups noted that patients struggle with anxiety so lowering PSA levels and increasing symptom control, as was demonstrated in Study COU-AA-302 aligns with patient values. Patient advocacy group input reported a wide variation in tolerance for side effects. However, pERC noted that patients who have had experience with abiraterone in later stages of mCRPC have generally found the side effects to be tolerable. Therefore, pERC concluded that abiraterone aligns with patient values.

pERC deliberated on the cost-effectiveness of abiraterone plus prednisone compared with prednisone alone, in the pre-chemotherapy setting. pERC noted that the economic analyses were strongly influenced by the estimates of overall survival, which was not statistically significant in Study COU-AA-302. This led to uncertainty in obtaining a precise estimate of the cost-effectiveness of abiraterone. However, pERC was satisfied that the Economic Guidance Panel (EGP) was able to estimate a range of possible incremental cost-effectiveness ratios using sensitivity analyses provided by the manufacturer. However, at the range of EGP estimates and the submitted price, pERC concluded that abiraterone could not be considered cost-effective compared with no treatment in the pre-chemotherapy setting. Upon review of feedback from the manufacturer on the EGP's best estimates, it was noted that although one of the EGP's estimates was $128,197, the EGP had also noted that there was considerable uncertainty surrounding this estimate and that if the survival benefit is less than assumed in the manufacturer's base case or if the

survival benefit attenuates over time, the ICER is likely much higher. Therefore, it was reiterated that the ICER is not likely $128,197 and will likely be greater than $175,000 per QALY.

pERC discussed the feasibility of implementing a recommendation for abiraterone. It was noted that abiraterone will be a new additional treatment and will not be replacing another treatment in this setting. In addition, the number of patients who would be treated with abiraterone in the pre-chemotherapy setting is larger than the number who are currently treated with abiraterone in the post-chemotherapy setting. Therefore, pERC considered that the budget impact of abiraterone could be substantial and provinces may want to take steps to limit budget impact such as implementing an approved prescriber list or other measures to prevent indication creep. In addition, pERC discussed that using abiraterone earlier in the treatment of mCRPC will likely lead to changes in the treatment algorithm for mCRPC. However, pERC noted that there is currently no evidence available to inform these changes and the impact of introducing abiraterone in the pre-chemotherapy setting on practice patterns is currently unknown. In particular, pERC concluded that the effectiveness of retreatment with abiraterone in the post-chemotherapy setting for patients who progressed following treatment with abiraterone in the pre-chemotherapy setting is currently unknown. Therefore, pERC could not make an informed recommendation on this issue.

EVIDENCE IN BRIEF

pERC deliberated upon:

- a pCODR systematic review
- other literature in the Clinical Guidance Report providing clinical context
- an evaluation of the manufacturer's economic model and budget impact analysis
- guidance from pCODR clinical and economic review panels
- input from two patient advocacy groups (Canadian Cancer Survivor Network, CCSN and Prostate Cancer Canada, PCC)
- input from pCODR's Provincial Advisory Group.

Feedback on the pERC Initial Recommendation was also provided by:

- the pCODR's Provincial Advisory Group
- two patient advocacy groups (Canadian Cancer Survivor Network, CCSN and Prostate Cancer Canada, PCC)
- the Submitter (Janssen Inc.)

The pERC initial recommendation was to fund abiraterone acetate conditional on the cost effectiveness being improved to an acceptable level. Funding should be for patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) after failure of androgen deprivation therapy (ADT), who have not received prior chemotherapy and who have ECOG performance status 0 or 1. Feedback on the pERC Initial Recommendation indicated that one patient advocacy group (PCC) and pCODR's Provincial Advisory Group agreed with the initial recommendation while the submitter and the second patient advocacy group (CCSN) agreed in part with the initial recommendation. The pERC Chair and pERC members reviewed the feedback and it was determined that the pERC Initial recommendation was eligible for early conversion to a pERC Final Recommendation without reconsideration by pERC because there was unanimous consensus from stakeholders on the recommended clinical population outlined in the pERC Initial Recommendation.

OVERALL CLINICAL BENEFIT

pCODR review scope

The pCODR review evaluated the efficacy and safety of abiraterone in combination with prednisone on patient outcomes compared to standard therapies or placebo in patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) who have failed on androgen deprivation therapy and have not received prior chemotherapy.

Studies included

The pCODR systematic review included one double-blind, randomized placebo-controlled trial (N=1088), Study COU-AA-302 (Ryan et al 2013), that evaluated the efficacy and safety of abiraterone acetate (1000 mg orally once daily) plus 5 mg prednisone compared to placebo plus 5 mg prednisone. After the second interim analysis (December 20, 2011) the data monitoring committee recommended unblinding Study COU-AA-302 and allowing cross-over of subjects from placebo to abiraterone, which confounded any subsequent analyses of overall survival.

Treatment was continued until confirmed radiographic progression of disease and/or unequivocal clinical progression, sustained side effects, withdrawal of patient consent, initiation of new anticancer treatment, or death.

Patient populations: patients with ECOG status 0 or 1 and no prior chemotherapy

pERC noted that the baseline characteristics of patients included in Study COU-AA-302 were generally well balanced across treatment groups. Patients were included in the trial if they had an ECOG performance status of 0 or 1 (76% and 24%, respectively) and failed on previous androgen deprivation therapy). Feedback from the Provincial Advisory Group was reviewed regarding ECOG performance status, prior androgen deprivation therapy and guidance around mildly symptomatic patients. It was noted that in the absence of data to support use of abiraterone in patients with ECOG performance status greater than 1, pERC was unable to make an inference for use in a broader patient population. It was also noted that the type of prior androgen deprivation therapy was not specified for entry in Study COU-AA-302, but usually includes LHRH or orchiectomy. However, it was noted that patients were included in Study COU-AA-302 if they had confirmed ongoing androgen deprivation with a serum testosterone level of less than 50 ng per deciliter (1.7 nmol per liter). Patients included in Study COU-AA-302 had no symptoms or were mildly symptomatic, as defined according to the Brief Pain Inventory–Short Form (BPI-SF) where asymptomatic patients had scores of 0 to 1 or mildly symptomatic patients had scores 2 to 3. Patients who had received prior chemotherapy or ketoconazole were excluded from the study.

Key efficacy results: consistent improvements in rPFS and secondary outcomes

Key outcomes deliberated on by pERC included overall survival (OS) and radiographic progression-free survival (rPFS), the co-primary endpoints of Study COU-AA-302, as well as other secondary outcomes. pERC noted that a statistically significant improvement in median rPFS was observed at the time of the second interim analysis (December 2011) for abiraterone versus placebo (16.5 months versus 8.3 months, HR=0.53, 95% CI 0.45 to 0.62, P<0.0001). However, for the other co-primary endpoint, overall survival, the prespecified boundary for statistical significance (P=0.0005) was not reached at either the second (prior to cross-over) or third interim analysis (following cross-over). pERC discussed that the decision to allow cross-over reduced the likelihood of obtaining significant overall survival results at subsequent analyses. However, pERC noted that there was a consistent and statistically significant benefit observed in the secondary outcomes, many of which were important to patients such as quality of life, median time to decline in functional status, median time to opiate use, PSA response and median time to PSA progression. Therefore, although the overall survival benefit of abiraterone is unclear, pERC considered that there is a clinical benefit associated with abiraterone in this setting.

Quality of life: decline in quality of life significantly delayed

pERC discussed quality of life data from Study COU-AA-302. Worsening of quality of life was defined as a decline of 10 or more points on the Functional Assessment of Cancer Therapy-Prostate (FACT-P) global score. The median time to FACT-P degradation was 12.65 and 8.31 months in the abiraterone and placebo group, respectively (HR=0.78, 95% CI 0.66 to 0.92, P=0.0028). pERC noted that a benefit was observed in all FACT-P categories except Social/Family Well Being. More specifically, a reduced risk of average pain intensity progression was observed (HR=0.82 P=0.049). pERC noted that these are outcomes that are important to patients and align with patient values. pERC also noted that by delaying initiation of chemotherapy, abiraterone is expected to improve quality of life by delaying exposure to the toxicities of chemotherapy.

Safety: well-tolerated with known and manageable toxicity profile

pERC discussed the toxicity profile of abiraterone acetate based on Study COU-AA-302 and concluded that the toxicities associated with abiraterone were tolerable. The most frequent adverse events included arthralgia, nausea and constipation, which is consistent with current experience in managing abiraterone therapy. Withdrawals due to adverse events were similar between abiraterone and placebo, except discontinuations due to hepatotoxicity were more common with abiraterone. pERC acknowledged that

abiraterone is currently used in the later stages of mCRPC, following chemotherapy. As a result clinicians will be familiar with the toxicity profile of abiraterone and be able to manage treatment related toxicities in asymptomatic or mildly symptomatic mCRPC patients.

Need: effective treatments that delay toxic chemotherapy treatments

Prostate cancer is the most commonly diagnosed cancer in men in Canada with 26,500 new cases and the third leading cause of cancer death in 2012. The majority of patients initially respond to androgen deprivation therapy but almost all eventually go on to develop castration resistant prostate cancer. These patients will need well-tolerated, effective treatments. pERC noted that patients with mCRPC who are asymptomatic or minimally symptomatic may receive hormonal therapies or be actively monitored for disease progression with no treatment. Chemotherapy with docetaxel is recommended for those with a good performance status. However, due to the toxicities associated with docetaxel, chemotherapy is often delayed as long as possible. In addition, docetaxel is a palliative treatment and eventually all patients develop progressive disease and are candidates for additional treatment. Based on patient advocacy group input, pERC noted that patients value a treatment option like abiraterone that delays disease progression and extends the time to chemotherapy use. In view of this, pERC acknowledged that abiraterone addresses a need in this patient population that would otherwise be followed with observation alone, or be treated with hormonal therapies until symptomatic disease progression requires treatment.

PATIENT-BASED VALUES

Values of patients with mCRPC: treatment options to delay progression or control symptoms

pERC discussed considerations important to patients and noted that patients with mCRPC value access to effective therapies that will stop progression of their disease and control symptoms. pERC acknowledged that patients value having access to treatment options and noted that abiraterone would be an effective treatment option for patients who would otherwise receive hormonal therapies or be monitored with no treatment until progression. pERC noted that patients valued access to new effective treatments that would allow patients to delay exposure to the toxicities associated with chemotherapy and provide relief long enough for other treatment options to emerge.

Patients value controlling mCRPC symptoms such as pain, fatigue, urinary incontinence, erectile dysfunction. pERC noted that patients struggle with the anxiety of increasing PSA levels. The ability of abiraterone to control PSA levels aligns well with patient values. In general, pERC discussed that based on the results of the COU-AA-302 study, abiraterone acetate demonstrated significant improvement in a number of outcomes important to patients and delayed declines in quality of life and the time to opiate use. Therefore, pERC considered that abiraterone aligns well with patient values.

Patient values on treatment: will tolerate side effects if treatment has benefits

pERC noted that patients with mCRPC are looking for treatments that will control overall net symptoms with minimal side effects and which are convenient to use. Although patients expressed a variety of tolerance levels for additional side effects with new treatment options, patients agreed that any additional side effects would need to be balanced with the benefit of the drug. pERC noted that Study COU-AA-302 demonstrated significant improvements in patient important outcomes such as quality of life and delaying time to opiate use, which aligns with patient values. Patients who had experience with abiraterone indicated that, overall, the side effects were tolerable. pERC also noted that physicians have experience with abiraterone in the later stages of mCRPC and overall the side effect profile is tolerable. pERC also noted that abiraterone is an oral treatment, which would be a convenient treatment option for patients. Therefore, this further strengthened pERC's conclusion that abiraterone aligns with patient values.

ECONOMIC EVALUATION

Economic model submitted: cost-effectiveness and cost-utility

The pCODR Economic Guidance Panel assessed a cost effectiveness analysis comparing abiraterone plus prednisone to prednisone alone for patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC) after failure of androgen deprivation therapy.

Basis of the economic model: clinical and economic inputs

Costs included drug costs, costs of managing adverse events, costs of disease-related follow up and subsequent treatments

Key clinical effects were overall survival and progression-free survival from the COU-AA-302 study.

Drug costs: list price of abiraterone submitted

At the submitted list price, abiraterone acetate costs $28.33 per 250 mg tablet. At the recommended dose of 1000 mg per day, the average cost per day in a 28-day course of abiraterone acetate is $113 and the average cost per 28-day course is $3,173.

Cost-effectiveness estimates: sensitive to overall survival during trial period

pERC deliberated on the cost-effectiveness of abiraterone plus prednisone compared with prednisone alone, in the pre-chemotherapy setting. pERC noted that the economic analyses were strongly influenced by the estimates of overall survival, the difference in which was not statistically significant in Study COU-AA-302. This led to uncertainty in obtaining a precise estimate of the cost-effectiveness of abiraterone. Using sensitivity analyses provided by the manufacturer, the Economic Guidance Panel (EGP) was able to determine a range of possible estimates of the incremental cost-effectiveness ratio. It was noted that the incremental cost-effectiveness ratio was more sensitive to changes in overall survival in the trial period compared with the post-trial period. The lower end of the EGP's range was similar to the manufacturer's estimated incremental cost-effectiveness ratio. However, pERC discussed the EGP's perspective that if the survival benefit is less than assumed in the manufacturer's base case or if the survival benefit attenuates over time, the ICER will be greater than $175,000 per QALY. Therefore, based on the range of EGP estimates and the submitted list price, pERC concluded that abiraterone could not be considered cost-effective compared with no treatment. Upon review of feedback from the manufacturer on the EGP's best estimates, it was noted that although one of the EGP's estimates was $128, 197, the EGP also noted that there was considerable uncertainty surrounding this estimate and that if the survival benefit is less than assumed in the manufacturer's base case or if the survival benefit attenuates over time. Therefore, pERC reiterated that the ICER is not likely $128,197 and will likely be greater than $175,000 per QALY.

ADOPTION FEASIBILITY

Considerations for implementation and budget impact: large budget impact and potential changes to treatment algorithms

pERC considered the feasibility of implementing a funding recommendation for abiraterone acetate and concluded that several factors would be important to consider.
pERC discussed the place in therapy of abiraterone and how this might impact its feasibility of adoption. pERC considered that as a new standard of care in patients who are asymptomatic or mildly symptomatic, abiraterone acetate could have a large budget impact. It was also noted that abiraterone will be a new additional treatment and would not be replacing another treatment in this setting. pERC acknowledged that there is likely a larger patient population that may qualify for abiraterone in the pre-chemotherapy setting as compared to the post-chemotherapy setting, where abiraterone has been used to date. Therefore, pERC considered that provinces may want to take steps to limit budget impact such as implementing an approved prescriber list or other measures to prevent indication creep. pERC noted that in some regions, abiraterone may be prescribed by both urologists and oncologists, which may create greater variability in how abiraterone is used.

pERC also discussed the potential impact of abiraterone in the pre-chemotherapy setting on downstream treatment algorithms. pERC acknowledged that this will likely require a change in the practice and treatment algorithms. However, pERC concluded the impact of using abiraterone in earlier treatment lines is as yet unknown and no evidence is available for making an assessment on the effectiveness of retreatment with abiraterone in the post-chemotherapy setting. Upon review of feedback from the Provincial Advisory Group, it was reiterated that optimal sequencing of therapy is currently unknown and there is no additional data available upon which pERC is able to provide further guidance on sequencing.

DRUG AND CONDITION INFORMATION

Drug Information	• Androgen inhibitor • Available as 250mg tablets • Recommended dose of 1000 mg per day
Cancer Treated	• Metastatic castrate resistant prostate cancer
Burden of Illness	• Prostate cancer is the most common cancer in men in Canada with 26, 500 new cases and the third leading cause of cancer death in 2012. • The majority of patients started on androgen deprivation therapy will develop castration resistant disease
Current Standard Treatment	• Hormonal therapies (e.g. steroids, ketoconazole, estrogen therapies) • Low dose prednisone • Monitoring or observation until chemotherapy required
Limitations of Current Therapy	• Limited effectiveness of therapies in pre-chemotherapy setting

ABOUT THIS RECOMMENDATION

The pCODR Expert Review Committee (pERC)

Recommendations are made by the pCODR Expert Review Committee following the pERC Deliberative Framework. pERC members and their roles are as follows:

Dr. Anthony Fields, Oncologist (Chair)
Dr. Maureen Trudeau, Oncologist (Vice-Chair)
Dr. Chaim Bell, Economist
Dr. Scott Berry, Oncologist
Bryson Brown, Patient Member
Mario de Lemos, Pharmacist
Dr. Sunil Desai, Oncologist
Mike Doyle, Economist
Dr. Bill Evans, Oncologist
Dr. Allan Grill, Family Physician
Dr. Paul Hoskins, Oncologist
Danica Lister, Pharmacist
Carole McMahon, Patient Member Alternate
Jo Nanson, Patient Member
Dr. Peter Venner, Oncologist
Dr. Tallal Younis, Oncologist

All members participated in deliberations and voting on the initial recommendation except:

- Jo Nanson, Dr. Chaim Bell and Dr. Sunil Desai who were not present for the meeting
- Dr. Peter Venner and Dr. Scott Berry who were excluded from voting due to a conflict of interest

Because the pERC Initial Recommendation met the criteria for early conversion to a pERC Final Recommendation, reconsideration by pERC was not required and deliberations and voting on the pERC Final Recommendation did not occur.

Avoidance of conflicts of interest

All members of the pCODR Expert Review Committee must comply with the *pCODR Conflict of Interest Guidelines*; individual conflict of interest statements for each member are posted on the pCODR website and pERC members have an obligation to disclose conflicts on an ongoing basis. For the review of abiraterone acetate (Zytiga) for metastatic castrate-resistant prostate cancer, through their declarations, four members had a real, potential or perceived conflict and based on application of the *pCODR Conflict of Interest Guidelines*, two of these members were excluded from voting.

Information sources used

The pCODR Expert Review Committee is provided with a *pCODR Clinical Guidance Report* and a *pCODR Economic Guidance Report*, which include a summary of patient advocacy group and Provincial Advisory Group input, as well as original patient advocacy group input submissions to inform their deliberations. pCODR guidance reports are developed following the pCODR review process and are posted on the pCODR website. Please refer to the pCODR guidance reports for more detail on their content.

Consulting publicly disclosed information

pCODR considers it essential that pERC recommendations be based on information that may be publicly disclosed. All information provided to the pCODR Expert Review Committee for its deliberations was handled in accordance with the *pCODR Disclosure of Information Guidelines*. There was no non-disclosable information in this recommendation document.

Use of this recommendation

This recommendation from the pCODR Expert Review Committee (pERC) is not intended as a substitute for professional advice, but rather to help Canadian health systems leaders and policymakers make well-informed decisions and improve the quality of health care services. While patients and others may use this Recommendation, it is for informational and educational purposes only, and should not be used as a substitute for the application of clinical judgment respecting the care of a particular patient, for professional judgment in any decision-making process, or for professional medical advice.

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