

Supplement 2. Disclosure of Interest Forms of the ASH Guideline Panel on Sickle Cell Disease- Related Pain

Amanda Brandow

Patrick Carroll

Susan Creary

Ronisha Edwards

Jeff Glassberg

Robert Hurley

Abdullah Kutlar

Eddy Lang

Jennifer Stinson

JJ Strouse

Fouza Yusuf

William Zempsky



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

I am passionate about the need for pain guidelines for patients with sickle cell disease.

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

I have presented research talks, posters, grand rounds talks and educational sessions focused on the study of pain in patients with sickle cell disease.

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

Funder	Description of Research	My Role	End Date
ASH	The Role of Substance P in the Pathophysiology of Pain in Sickle Cell Disease	Principal Investigator	June 2017
NIH/NHLBI	Peripheral Sensitization as a Novel Mechanism for Pain in Sickle Cell Disease	Principal Investigator	May 2018
Greater Milwaukee Foundation	Investigating the role of inflammation in acute and chronic sickle cell disease pain	Principal Investigator	December 2021

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don’t know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

Don't know

No

Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

I have strong support from my primary mentor and institution to be involved in the development of these guidelines.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Pediatric Benign Hematology

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

I treat children with sickle cell disease who have acute and chronic pain

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
N/A	Appointed to serve on the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force. Her term will end in July 2019. The Task Force is charged with determining whether there are gaps or inconsistencies in pain management across Federal agencies. If there are, the group will propose updates and develop a strategy for disseminating the updates.	2/26/18	Not a conflict. The Department of Health and Human Services is not a for-profit company.
N/A	Funding from National Institutes of Health/National Heart Lung and Blood Institute (NIH/NHLBI) to investigate the role of the microbiome and inflammation in acute and chronic pain in patients with sickle cell disease. Dr. Brandow is the Principal Investigator and the grant is expected to end August 2023.	10/30/18	Not a conflict. The National Institutes of Health/National Heart Lung and Blood Institute is not a for-profit company.
N/A	Appointed to serve on Centers for Disease Control (CDC) Opioid	7/6/18	Not a conflict. The Centers for Disease

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	<p>Prescribing Estimates Workgroup. Appointed as core workgroup member by Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, National Center for Injury Prevention and Control. The workgroup is charged with determining prescribing estimates for opioids for a variety of pain conditions including sickle cell disease.</p>		<p>Control is not a for-profit Company.</p>
<p>N/A</p>	<p>Funding from the National Institutes of Health and the National Institute of Neurological Disorders and Stroke (NIH/NINDS) to investigate inflammatory index as a biomarker for pain in patients with sickle cell disease. The overall goal of this award is to discover an inflammatory prognostic biomarker for sickle cell pain. Dr. Brandow is a multiple principal investigator (MPI), and the grant is expected to end 7/31/2022.</p>	<p>11/15/2019</p>	<p>Not a conflict. The National Institutes of Health/National Institute of Neurological Disorders and Stroke is not a for-profit company.</p>

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 9/13/16; Kunkle, 9/13/16	No	No	
Webb 1/9/18; Kunkle 1/24/18; Lottenberg 1/28/18	No	No	Transferred disclosures to new form. Added “Other Notes” below.
Webb, Kunkle 4/2/18	No	No	See new disclosure added in Part D above.
Webb, 10/31/18	No	No	See new disclosure added in Part D above.
Russell, Kunkle 11/20/19	No	No	See new disclosure added in Part D above. Dr. Brandow confirmed all other information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Brandow is a specialist in pediatric benign hematology. In her clinical practice, she treats children who have acute and chronic pain. She is the principal investigator on research projects relevant to this guideline topic: (1) the role of Substance P in the pathophysiology of pain in SCD, funded by ASH; (2) peripheral sensitization as a novel mechanism for pain in SCD, funded by the National Heart, Lung and Blood Institute; (3) the role of inflammation in acute and chronic sickle cell disease pain, funded by the Greater Milwaukee Foundation. She has given scientific and educational presentations about pain in patients with SCD. In 2018 she was appointed to serve on the HHS Pain Management Best Practices Inter-Agency Task Force.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

(I may hold index funds with such stocks, but their management is automated and I have no knowledge or control of which stocks are included nor how they are traded)

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>
			Per note above, shares of companies owned in diversified mutual funds managed by a third party are not considered a conflict.

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Published in Pain Management in 2011 under the title "Sickle Cell Disease: Time to Act." In brief, that SCD pain is complex, severe, and important from a basic science perspective and that greater clinical and basic research attention needs to be applied.

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
Blaustein Pain Research Fund	Examining the role of socioeconomic, psychiatric, and pain-related cognitive variables on opioid responsivity for vaso-occlusive crisis	PI	Ongoing
Blaustein Pain Research Fund	Examining mechanisms of latent opioid induced hyperalgesia	PI	Ongoing

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

Don't know

No

Yes

If yes, please explain:

I bill for clinical services.

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

I believe support would be clear and wholehearted. My mentorship and institutional team are equally dedicated to improving the care of people with SCD.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Psychiatry, with expertise in pain and addictions.

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

As part of our multidisciplinary team, I often make recommendations for the management of pain and modify behavioral and pharmacological plans for individual patients; as well as guiding clinic policy and practice.

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
n/a	Dr. Carroll received honoraria from universities for speaking engagements on pain management in SCD.	11/24/2019	

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/3/17; Panepinto 3/4/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	No	
Russell 11/25/19	No	No	New disclosure. See Part D above. On 1/12/2020, Dr. Carroll confirmed all information on this form is correct.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Carroll is a psychiatrist who specializes in pain and addictions. In his clinical practice, he often makes recommendations for the management of pain as well as guides policy and practice of his clinic. He is the principal investigator for two research studies relevant to SCD pain, funded by the Blaustein Pain Research Fund: (1) the role of socioeconomic, psychiatric, and pain-related cognitive variables on opioid responsivity for vaso-occlusive crisis and (2) mechanisms of latent opioid-induced hyperalgesia. In 2011, he authored an editorial about SCD pain titled "Sickle Cell Disease: Time to Act," published in the journal *Pain Management*.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
----------------	--------------------------------	----------------	-----------------	-----------------------------

<p>Pfizer</p>	<p>Phase 3 study of investigational agent to determine if it reduces LOS for acute pain crises in patients with sickle cell disease</p>	<p>Site Co-I</p>	<p>ongoing</p>	<p>Indirect conflict. Pfizer markets pain medications (e.g., oxycodone). These guidelines will offer recommendations about classes of pain medication; however, because SCD is a rare disease, and because pain medications are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Creary does not have a direct financial relationship with the company, and this research is unrelated to opioids. Pfizer is also developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p>
---------------	-----------------------------------------------------------------------------------------------------------------------------------------	------------------	----------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
				Dr. Creary does not have a leadership role in this research.

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

I helped to create the ASH Pocket Guideline for Hydroxyurea and Transfusion in Children and Adults with SCD.

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know
- No
- Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

My institution and mentors would be very supportive of my participation in this guideline panel, regardless of whether it received a strongly positive or negative reaction from peers outside my institution.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

- No
- Yes

If yes, what is your primary specialty or subspecialty?

Pediatric Hematology and within hematology, I primarily see children with sickle cell disease.

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

- No
- Yes

If yes, please explain:

Yes, I prescribe or otherwise recommend clinical interventions that may be addressed by these guidelines. I primarily care for children with sickle cell disease and the most common complications of this disease is pain. I anticipate that this panel will help to will help to provide more clarity about interventions to diagnose, prevent and treat acute pain in patients with sickle cell disease, as currently, specific guidelines for diagnosis and management do not exist.

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

- No
- Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
N/A	Dr. Creary reports that she is the PI on an NIH/NHLBI-funded project to prospectively study a multidimensional and electronic intervention to improve hydroxyurea adherence in children with sickle cell disease. The expected end date is 5/31/2020.	7/22/19	
N/A	Dr. Creary reports that she is the PI on an NIH/NHLBI-funded project to develop a Comprehensive Program to Increase Sickle Cell Trait Knowledge and Awareness Among Parents of Infants Identified by Newborn Screening. The expected end date is 3/31/2021.	7/22/19	
Novartis	Open Payments reports food and beverage on 8/2/2017.	7/22/19	Indirect conflict. Novartis markets non-opioid pain medications (e.g., paracetamol). These guidelines offer recommendations about classes of pain medication; however, because SCD is a rare disease, and because

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
			<p>pain medications are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Finally, there is probably little risk of perceived conflict around non-opioid pain medications.</p> <p>Novartis also markets products for iron overload, a complication of transfusion. These guidelines do not address management of iron overload but do address monthly transfusion for pain. Although SCD is a rare condition, the company could be indirectly affected by a recommendation to do or not do transfusion.</p> <p>Novartis also owns Selexys Pharmaceuticals, which is investigating an anti-P-selectin antibody (SelG1) to prevent vaso-occlusive crises. This drug is not yet to market and is not be specifically addressed by these guidelines. However, the company could be indirectly affected by any recommendations that implicitly or explicitly suggest a need for</p>

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
			therapies to prevent painful vaso-occlusive crises.
Emmaus Medical, Inc	Open Payments reports food and beverage on 6/20/2018.	7/22/19	Indirect conflict. Emmaus Medical markets L-glutamine, which was approved by FDA in 2017 for preventing acute vaso-occlusive events in children and adults with SCD. This product is not specifically addressed by the guidelines.

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/30/17; Panepinto 3/31/17; Kunkle 1/24/18; Lottenberg 1/28/18	No	Yes	<p>Dr. Creary is a site co-investigator on a clinical trial of an investigational agent for acute pain in patients with SCD, funded by Pfizer. Pfizer markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Creary does not have a direct financial relationship with the company, and this research is unrelated to opioids.</p> <p>Pfizer is developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p> <p>This indirect conflict will be managed by disclosure and by panel composition. Recusal will not be required.</p>
Kunkle, Russell 11/7/2019; Russell 1/10/2020	No	Yes	<p>In July 2019, Dr. Creary reported new indirect conflicts with Novartis and Emmaus Medical. See Part D above.</p> <p>As noted above, Dr. Creary has received direct payments from Novartis. On Nov 15, 2019, Novartis received approval from FDA to market its drug crizanlizumab to reduce frequency of</p>

			<p>vaso-occlusive crises in patients with SCD. The guidelines do not offer specific recommendations about this drug because it was not yet to market during question formulation or evidence review.</p> <p>Dr. Creary confirmed all other information on this form.</p>

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Creary is a hematologist who primarily sees children with SCD. In her clinical practice, she prescribes or recommends clinical interventions for SCD-related pain. She authored a pocket guide on hydroxyurea and transfusion in children and adults with SCD, published in 2014 by ASH, which was based on 2014 guidelines of the National Heart, Lung and Blood Institute.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know
- No
- Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

I am supported by everyone with my involvement of these guidelines.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/6/17; Panepinto, 3/8/2017; 1/23/18 Kunkle; Lottenberg 1/28/18	No	No	
Russell, Kunkle 11/4/2019	No	No	Ms. Edwards confirmed that all information on this form is correct.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

--



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
NHLBI	Clinical Trial	PI	July 2018

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know
- No
- Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

Strong

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Emergency Medicine

Ambulatory Sickle Cell Care

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
Pfizer	Site PI for the RESET Trial, a Phase 3 clinical trial of rivipansel for vaso-occlusive crisis. Funding goes to his institution.	3/23/2018	Indirect conflict. Pfizer markets pain medications (e.g., oxycodone) and is developing new drugs including rivipansel for treatment of vaso-occlusive crisis in SCD.
Pfizer	PI of research grant (\$50,000 ending in November 2019) called "system level informatics to improve ED care of VOC". Funding goes to his institution.	10/5/18	Indirect conflict, as noted above Pfizer could be indirectly affected by these guidelines.
Synergy Pharmaceuticals Inc	Open Payments reports that Dr. Glassberg received food and beverage from Synergy on 9/6/2017. He does not recall this.	7/19/19	Synergy filed for bankruptcy in December 2018, and the company's assets were later sold to Bausch Health.
Pfizer	Dr. Glassberg reports that funding for the RESET trial is complete and participation has ended.	7/19/19	See above. This research activity occurred during the guideline development process.

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/3/17; Panepinto 3/4/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	No	
Webb 3/23/18; Kunkle 4/3/18	No	Yes	See new disclosure in Part D above. Dr. Glassberg is now a site investigator on a Phase 3 clinical trial of rivipansel for treatment of vaso-occlusive crisis in patients with SCD, funded by Pfizer. All funding goes to his institution. In addition to investigating rivipansel and other new drugs for SCD, Pfizer markets opioid pain medications (e.g., oxycodone). This indirect conflict will be managed by disclosure and by panel composition. Recusal will not be required.
Webb 10/31/18	No	Yes	See new Pfizer disclosure above in Part D. Dr. Glassberg is the Principal Investigator for a research grant on emergency department care of vaso-occlusive crisis. All funding goes to his institution. In addition to investigating rivipansel and other new drugs for SCD, Pfizer markets opioid pain medications (e.g., oxycodone). This indirect conflict will be managed by disclosure and by panel composition. Recusal will not be required.
Russell, Kunkle 11/25/2019	No	Yes	New disclosures on 7/19/19. See Part D above. On 11/25/19, Dr. Glassberg confirmed all information on this form is correct.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Glassberg's clinical specialty is emergency medicine and ambulatory sickle cell care. He is the principal investigator for a research study funded by the National Heart, Lung and Blood Institute about risk factors for emergency department utilization in patients with SCD.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>
University of Florida	Patent Pending #13/817,165 - development of a monitor to assess respiration and ETCO2		Not a conflict. University of Florida is not an affected company and the patent is still pending.

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
Pfizer IGLC	RCT-examining education of primary care physicians and implementation of electronic patient reported health outcome measures	Co-PI	9-2015	Ended before appointment.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
AHRQ	Examination of pain treatment guideline adherence in primary care clinicians	Co-I	2020
Faye-McBeath Foundation	Education of clinical providers on non-opioid pain treatment strategies	PI	10-2016

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know

No

Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

The institution and departmental chair would be supportive of the positions held by my authorship related to sickle cell pain and treatment.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Pain Management

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

I prescribe (or refer for) pain psychology services, social services, pharmacological treatments and medical services for patients with the sickle cell disease. I use patient reported outcomes to help guide my clinical treatment and this could be discussed in these guidelines. I recommend integrated health approaches to care including biofeedback and mindfulness meditation that could be discussed. I prescribe medications to treat SCD related pain and these will likely be discussed in these guidelines.

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
n/a	Dr. Hurley, previously with the Medical College of Wisconsin, is now with Wake Forest School of Medicine.	1/28/18	Not a conflict. Header updated.
n/a	Dr. Hurley is a co-investigator on a new research project, funded by NIH/NIDA (1R21DA046085-01): Nudging Primary Care Providers Toward Guideline-Recommended Opioid Prescribing through Easier and more Convenient HER Information Design End Date: 10/31/2019	1/28/18	Not a conflict.
Medtronic	Dr. Hurley is the Principal Investigator for an educational grant for his institution's pain medicine fellowship. All funding goes to his institution and is incorporated into the funding sources for the fellowship.	11/1/18	Indirect conflict. Medtronic markets a targeted drug delivery pump for chronic pain. The product is not specific to sickle cell disease; however, the company could be indirectly affected by recommendations for or against the use of opioids for chronic SCD pain.
n/a	Dr. Hurley is a Robert Wood Johnson Foundation (RWJF) Scholar. The Foundation funds a	11/1/18	Not a conflict. RWJF is a not-for-profit foundation.

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	clinical project to improve opioid addicted veteran's care in the community. This is a community engagement project and is not related to SCD.		
Medtronic (MDT)	Dr. Hurley is research consultant for MDT for predictive research consultation on predictive analytics for SCS. Appointment anticipated to end in 2020. (Open Payments reports direct transfers of value to Dr. Hurley in 2017 and 2018.)	7/19/2018	Not a conflict. Medtronic markets devices used to deliver pain medication (e.g., neurostimulators and drug pumps). Although these guidelines address the implementation of pharmacological pain management, such as time to dose and mode of administration, they do not address specific delivery devices. Furthermore, because SCD is a rare condition, the impact on the company of a recommendation for or against a modality such as pain medication delivered by drug pump is expected to be trivial. Finally, there is probably little risk of perceived conflict around modalities for delivery of pain medication.
Avanos	Dr. Hurley is the PI in industry-funded institutional research on: A Prospective, Multi-center, Randomized, Assessor Blind, Controlled Study	7/19/2018	Indirect conflict. Avanos markets pain management devices for acute and chronic pain, such as thermal radiofrequency systems. The subject of

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	Comparing Lateral Branch Cooled Radiofrequency Denervation to Conservative Therapy as Treatment for Sacroiliac Joint Pain in a Military and Civilian Population. Anticipated end date is 2020.		this research is relevant to the guidelines, and Dr. Hurley has a leadership role.

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/2/17; Panepinto 3/8/17	No	No	
Kunkle 1/24/18; Lottenberg 1/28/18	No	No	New disclosure (not a conflict). See Part D, above. Added "Other Notes" below.
Webb 11/1/18; Kunkle 11/6/18	No	Yes	See new disclosures in Part D above. Dr. Hurley is the PI for a grant from Medtronic. All funding goes to his institution to support their fellowship program. Medtronic markets a drug delivery pump for chronic pain. This product is not specific to sickle cell disease; however, the company could be indirectly affected by recommendations for or against the use of opioids in SCD patients with chronic pain. This indirect conflict will be managed by disclosure and panel composition. Recusal will not be required.
Russell, Kunkle 1/7/2020	No	Yes	Dr. Hurley confirmed all information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Hurley is a professor of anesthesiology and the director of a pain service at his institution. In his clinical practice, he evaluates and treats patients with SCD for pain, including using medications and integrated health approaches. He is a co-investigator on a study of adherence by primary care clinicians to pain treatment guidelines, funded by the Agency for Healthcare Research and Quality. He is the principal investigator on a study of education of clinicians about non-opioid pain treatment strategies, funded by the Faye-McBeath Foundation. And He is a co-investigator on a study about the use of health information technology to nudge primary care providers toward guideline-recommended opioid prescribing, funded by the National Institute on Drug Abuse. And as a Robert Wood Johnson Foundation scholar, he is working on a community engagement project for veterans who use opioids.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
Novartis Pharmaceuticals	Consultant	ongoing	<p>Indirect conflict. Novartis markets non-opioid pain medications (e.g., paracetamol). These guidelines will offer recommendations about classes of pain medication; however, because SCD is a rare disease, and because pain medications are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Finally, there is probably little risk of perceived conflict around non-opioid pain medications.</p> <p>Novartis also markets products for iron overload, a complication of transfusion. These guidelines will not address management of iron overload but will address monthly transfusion for pain. Although SCD is a rare condition, the company could be indirectly affected by a recommendation to do or not do transfusion.</p>

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
			<p>Novartis also owns Selexys Pharmaceuticals, which is investigating an anti-P-selectin antibody (SelG1) to prevent vaso-occlusive crises. This drug is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by any recommendations that implicitly or explicitly suggest a need for therapies to prevent painful vaso-occlusive crises.</p>
Vertex Pharmaceuticals	Advisory Board	11/7/2016	Ended before appointment.
Cerus Corporation	Advisory Board	12/2/2016	Ended before appointment.
Sancilio & Company Inc.	Consultant	Ongoing	<p>Indirect conflict. Sancilio is developing a proprietary fatty acids product (Altemia) for the treatment of SCD including reduction of pain episodes. This product is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly suggest a need for new therapies to reduce SCD pain.</p>

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner's or Spouse's Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
Novartis Pharmaceuticals	Panobinostat in SCD	PI	12/31/16	Ended before appointment.
Gilead Sciences	Phase-I study of ET-A receptor antagonist Ambrisentan. Funded by NHLBI and Gilead donated the study drug.	PI	Ongoing	Not a conflict. Gilead does not market and is not investigating any products for SCD.
Pfizer Inc.	Rivipansel in SCD-Phase-III	Site Investigator	Ongoing	Indirect conflict. Pfizer markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
				<p>rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Kutlar does not have a direct financial relationship with the company, and this research is unrelated to opioids.</p> <p>Pfizer is also developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat</p>

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
				painful vaso-occlusive crises. Dr. Kutlar does not have a leadership role in this research about rivipansel.

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Book Chapter (Williams Hematology, 9th Ed. 2015)

Editorial Comment. (Blood, 2013)

Oral and Poster Presentations (ASH Annual Meetings)

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
NIH/NHLBI	Role of Endothelin (Ambrisentan) in Sickle Cell Disease	Contact PI	5/31/2018
NIH/NHLBI	SCD Implementation Consortium	Contact PI	Ongoing

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

Don't know

No

Yes

If yes, please explain:

Clinical activity. Grant funding

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

Will be supportive

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Hematology

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Opioids, hydroxyurea, other adjuvant pain meds

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
Novartis/Selexys	Consultant	4/3/17	Indirect conflict. As described above in Part A, Question 4, Novartis/Selexys could be indirectly affected by these guidelines.
Sancilio	Consultant	4/3/17	Indirect conflict. As described above in Part A, Question 4, Sancilio could be indirectly affected by these guidelines.
Micelle Biopharma	Sancilio has been taken over by Micelle Biopharma as of 8/9/18.	10/11/18	Indirect conflict. The Altemia product formerly of Sancilio has been acquired by Micelle Biopharma. Like Sancilio, the Altemia product is not to market but Micelle Biopharma could be indirectly affected by recommendations that implicitly or explicitly suggest a need for new therapies to reduce SCD pain.
Novartis Pharmaceuticals	Dr. Kutlar is the PI in an ongoing study on Crizanlizumab in SCD	7/26/2019	Indirect conflict. As noted above, Dr. Kutlar has received direct payments from Novartis. On Nov 15, 2019, Novartis received approval from FDA to market

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
			its drug crizanlizumab to reduce frequency of vaso-occlusive crises in patients with SCD. The guidelines do not offer specific recommendations about this drug because it was not yet to market during question formulation or evidence review.
Global Blood Therapeutics	Dr. Kutlar is the PI for a trial on GBT440-037 in SCD. This trial is part of an Expanded Access Program (EAP). Anticipated end date is by the end of 7/2019.	7/26/2019	Indirect conflict. Global Blood Therapeutics is developing GBT 440, a potentially disease-modifying therapy for SCD. This drug is not yet to market and is not be specifically addressed in these guidelines; however, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for a disease-modifying therapy that might prevent disease complications including pain.
Bluebird Bio	Dr. Kutlar is an ongoing DSMB Member.	7/26/2019	Not affected company. Bluebird Bio is developing a gene editing platform for use in SCD patients. Although gene therapy is not addressed in this guideline, the company could be indirectly affected by recommendations

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
			that implicitly or explicitly identify a need for a disease-modifying therapy that might prevent disease complications including pain.
Kite	Open Payments reports that Dr. Kutlar received food and beverage on 10/9/2018.		Kite (owned by Gilead) does not market products for SCD or for pain.
Novartis	Open Payments reports that Dr. Kutlar received direct payments or other transfers of value including food and beverage and travel and lodging during 2017 and 2018.		Indirect conflict. Dr. Kutlar previously reporting consulting for Novartis. See Part A, Question 4.
Shire	Open Payments reports that Dr. Kutlar received food and beverage from Shire on 12/10/2018.		Shire was acquired by Takeda in late 2018. Neither company markets products for SCD or for pain.
Terumo BCT	Open Payments reports that Dr. Kutlar received direct payments on 7/6/2018.		Direct conflict. Terumo markets a protocol and system for red blood cell exchange transfusion in patients with SCD. These guidelines address transfusion for pain management in patients with SCD.
Novo Nordisk	Open Payments reports that Dr. Kutlar received food and beverage from Novo Nordisk on 10/12/2017.		Indirect conflict. Novo Nordisk is investigating a disease modifying therapy for SCD.
Incyte Corporation	Open Payments reports that Dr. Kutlar received food and beverage on 12/9/2017.		Indirect conflict. Incyte is developing targeted therapies for SCD.

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
n/a	Dr. Kutlar disclosed that he is no longer a consultant for Sancilio & Company Inc. as of 8/7/2018.	12/3/2019	
n/a	Dr. Kutlar confirmed that his term as site investigator for Pfizer Inc ended on 9/20/2019.	12/3/2019	
Global Blood Therapeutics	Dr. Kutlar noted that his role as the PI for the above-described GBT-funded trial of voxelotor (GBT440-037) is ongoing. Voxelotor was approved by FDA on November 25, 2019.	1/13/2020	Indirect conflict , as disclosed and explained above.

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 4/24/17; Panepinto 4/24/17; Webb 12/19/17; Kunkle 1/24/18; Lottenberg 1/28/18	No	Yes	<p>Dr. Kutlar receives direct payments from Novartis/Selexys and from Sancilio, and he is an investigator for a research study about rivipansel that is funded by Pfizer. These companies could be indirectly affected by these guidelines, as follows:</p> <p>Novartis markets products for iron overload, a complication of transfusion. These guidelines will not address management of iron overload but will address monthly transfusion for pain. Although SCD is a rare condition, the company could be indirectly affected by a recommendation to do or not do transfusion.</p> <p>Selexys Pharmaceuticals, which is owned by Novartis, is investigating an anti-P-selectin antibody (SelG1) to prevent vaso-occlusive crises. This drug is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by any recommendations that implicitly or explicitly suggest a need for therapies to prevent painful vaso-occlusive crises.</p> <p>Sancilio is developing a proprietary fatty acids product (Altemia) for the treatment of SCD including reduction of pain episodes. This product is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly suggest a need for new therapies to reduce SCD pain.</p> <p>Pfizer is developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating</p>

			<p>efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p> <p>These indirect conflicts will be managed by disclosure and by panel composition. Recusal will not be required.</p> <p>Pfizer also markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Kutlar does not have a direct financial relationship with the company, and his research is unrelated to opioids.</p>
Webb 11/1/18	No	Yes	<p>See new disclosure in Part D. above. Sancilio has been taken over by Micelle Biopharma. Micelle has obtained the rights to Sancilio's pipeline sickle cell drug Altemia for pain. This product is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly suggest a need for new therapies to reduce SCD pain.</p> <p>These indirect conflicts will be managed by disclosure and by panel composition. Recusal will not be required.</p>
Russell, Kunkle 1/14/20	Yes	Yes	<p>See new disclosures in Part D above (July 2019 through January 2020), including a new direct financial conflict (with Terumo) that occurred before the guideline panel formed recommendations and new indirect conflicts (with Novartis, Global Blood Therapeutics, Novo Nordisk, and Incyte) occurring after the panel formed recommendations. On January 14, 2020, Dr. Kutlar confirmed all information on this form.</p>

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Kutlar is a hematologist who sees and treats patients with SCD. In his clinical practice, he prescribes or recommends opioids, hydroxyurea, and other adjuvant pain medications. In addition to the industry-funded research described above, he is an investigator on SCD research projects funded by the National Heart, Lung and Blood Institute. He has given presentations and authored editorials and book chapters on SCD pain.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
EBSCO – Dynamed	Recommendations editor	ongoing	Not a conflict. EBSCO markets library database services and publishes medical reference works including Dynamed. The company has no products that will be affected by these guidelines.

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

No

Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

Don't know

No

Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

Don't know

No

Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Emergency Medicine

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/2/17; Panepinto 3/4/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	No	
Russell, Kunkle 11/25/2019	No	No	Dr. Lang confirmed all information on this form is correct.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Lang is an emergency medicine physician and expert in guideline methodology.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

- a) Research Report: Odame, I, **Stinson, J**, et al. (2016). Quality-Based Procedures Clinical Handbook for Sickle Cell Disease Vaso-occlusive Crisis. Provincial Council for Maternal and Child Health & Ministry of Health and Long-Term Care, Toronto, Canada.
- b) Journal Article: **Stinson, J**, Naser, B. (2003). Pain management in children with sickle cell disease. *Pediatric Drugs*, 5(4):229-241.

- c) Journal Article: **Stinson, J** & Naser, B. (2000). Analgésie autocontrôlée chez les enfants atteints d’anémie falciforme: l’expérience d’un center canadien. *Douleur et Analgesie*, 13(1):21-26.
- d) Conference Abstract: **Stinson, J**, Naser, B. (1999). Patient controlled analgesia in patients with sickle cell disease: A retrospective analysis of one centre’s experience. *Pain Research & Management*, 4(1): Abstract 72, 60.
- e) Conference Poster: [Poster]. **Stinson, J**, Naser, B. (1999 & 2000). Patient controlled analgesia in children with sickle cell disease: A retrospective analysis of one centre’s experience. The 5th International Symposium on Pediatric Pain, London, United Kingdom, June 18 – 21, 2000; The 9th World Congress on Pain, Vienna, Austria, August 1999; and The Annual Conference of The Canadian Pain Society, May 1999, St. John’s, Newfoundland.

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
Eunice Kennedy Shriver National Institute of Child Health and Human Development	iCanCope with Sickle Cell Disease	Principal Investigator (along with Tonya Palermo and Carlton Dampier)	2021

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don’t know

No

Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

Don't know

No

Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

WOULD BE SUPPORTED.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

PEDIATRIC CHRONIC PAIN.

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
Pfizer	Dr. Stinson is the Principal Investigator for Skype-based Peer to Peer Support (iP2P) Program for youth with Sickle Cell Disease: A Feasibility Randomized Controlled trial. This is an unrestricted research grant from Pfizer's Aspire Sickle Cell Research Grant. All funding goes directly to her institution.	10/31/18	Indirect conflict. Pfizer markets opioid and non-opioid pain medications (e.g., oxycodone, and gabapentinoids). These guidelines will offer recommendations about both classes of drugs. However, SCD is a rare disease, and because opioids and non-opioid pain relievers are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Pfizer is also developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
			<p>specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p> <p>Dr. Stinson's research is unrelated to any of the above drugs, and funding from Pfizer goes to her institution, not to her directly.</p>

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 2/23/17; Panepinto 3/4/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	No	
Webb, Kunkle 11/6/18	No	Yes	<p>See new disclosure in Part D above. Dr. Stinson is the PI on an unrestricted research grant titled Skype-based Peer to Peer Support (iP2P) Program for youth with Sickle Cell Disease, funded by Pfizer.</p> <p>Pfizer markets opioid and non-opioid pain medications (e.g., oxycodone, and gabapentinoids), and the company is investigating new drugs (rivipansel, PF-04447943) for the prevention and treatment of vaso-occlusive crisis in SCD.</p> <p>The subject of Dr. Stinson's research is unrelated to the above drugs, and all funding goes to her institution. This indirect conflict will be managed through disclosure and panel composition. Recusal will not be required.</p>
Kunkle 3/4/2020	No	Yes	On 3/4/19, Dr. Stinson confirmed all information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Stinson is a nurse clinician-scientist who specializes in pediatric chronic pain. She is a co-principal investigator for a research project about a tailored web and smartphone-based application (iCanCope with SCD) to improve pain self-management and functioning in youth (aged 12-18) with the disease. The project is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development. Dr. Stinson has published guidance documents and editorials about pain management in patients with SCD.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>
General Electric	Stock		Not a conflict. GE Healthcare markets a variety of products and technologies used in hospital and other clinical settings, but none of these products is specific to SCD or to pain management for SCD populations.
Medtronic	Stock		Not a conflict. Medtronic markets devices used to deliver pain medication (e.g., neurostimulators and drug pumps). Although these guidelines will address the implementation of pharmacological pain management, such as time to dose and mode of administration, they will not address specific delivery devices. Furthermore, because SCD is a rare condition, the impact on the company of a recommendation for or against a modality such as pain medication delivered by drug pump is expected to be trivial. Finally, there is probably little risk of perceived conflict around modalities for delivery of pain medication.

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
----------------	--------------------------------	----------------	-----------------	-----------------------------

Pfizer	Clinical trial of rivipansel	Site Co-investigat or without financial support	current	<p>Indirect conflict. Pfizer markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Strouse does not have a direct financial relationship with the company, and this research is unrelated to opioids.</p> <p>Pfizer is also developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p>
--------	------------------------------	-------------------------------------------------	---------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
				Dr. Strouse does not have a leadership role in this research about rivipansel.
Global Blood Therapeutics	Clinical trial of GBT-440	site co-investigat or, no financial support	pending	Indirect conflict. Global Blood Therapeutics is developing GBT 440, a potentially disease-modifying therapy for SCD. This drug is not yet to market and will not be specifically addressed in these guidelines; however, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for a disease-modifying therapy that might prevent disease complications including pain. Dr. Strouse does not have a leadership role in this research on GBT 440.

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
Advanced Studies in Medicine	Medical director for hemophilia CME activities, moderator	Paid	4/15/16	Not a conflict. <i>Advanced Studies in Medicine</i> is a journal published by the Johns Hopkins University School of Medicine.

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain: Use of both non-opiate and opiate treatment approaches to manage chronic sickle cell pain

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made? Sickle cell pain treatment presented based on NHLBI guidelines at multiple grand rounds, resident lectures

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know
- No
- Yes

If yes, please explain: I provide care for people with sickle cell and pain

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution? I expect that I would be supported as long as the guidelines were developed using rigorous methodology

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions. I am the treasurer

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>
Sickle Cell Adult Provider Network	Organized several symposiums on pain management for adults with sickle cell disease. Advocates for	Treasurer, member of board-helps to choose symposium topics

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>
	access to acute pain management following NHLBI guidelines	

Clinical Practice

9. Do you see patients clinically?

- No
 Yes

If yes, what is your primary specialty or subspecialty? Hematology/Pediatric Hematology/Oncology

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

- No
 Yes

If yes, please explain: I see children and adults with sickle cell disease and routinely treat them (or supervise their treatment or refer them for treatment) for acute and chronic pain.

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

- No
 Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
Medtronic	Dr. Strouse reported that he divested his stock on 6/6/17	2/22/2018	Not a conflict, as noted above.
Global Blood Therapeutics	Dr. Strouse reported that he expects to do paid consulting.	4/23/2018	Indirect conflict
Global Blood Therapeutics	Dr. Strouse reports direct payments for consulting and speaking for GBT's Access to Care Conference in September 2018 and travel and lodging for the September 2019 conference.	11/13/2019	Indirect conflict
CME Outfitters	Dr. Strouse reports direct payments for a CME activity about the treatment of sickle cell in the emergency department. This activity was supported by an educational grant from CSL Behring LLC and Shire, now part of Takeda.	11/13/2019	Not a conflict. CME Outfitters is an accredited CME provider.
Potomac CME	Dr. Strouse reports that he gave three CME lectures on the treatment of sickle cell disease for Potomac CME supported by an educational grant to them from Novartis.	11/13/2019	Not a conflict. Potomac CME is an ACCME-accredited provider of medical education.

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
Takeda	Dr. Strouse reports that he is in the process of becoming a site PI for the Takeda study of SHP655 (recombinant ADAMTS13), a Phase I/II study for the treatment of people with sickle cell disease admitted with pain.	11/13/2019	Indirect conflict. SHP655 has been granted fast track approval by FDA for patients with hereditary thrombotic thrombocytopenic purpura. This therapy is only under investigation to treat pain in patients with SCD. The therapy is not yet to market and is not addressed by the guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat pain. Funding for this research goes to Dr. Strouse's institution, not to him directly.

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/2/17; Panepinto 3/8/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	Yes	<p>Dr. Strouse is a site co-investigator on a clinical trial of rivipansel, funded by Pfizer. Pfizer markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Dr. Strouse does not have a direct financial relationship with the company, and this research is unrelated to opioids.</p> <p>Rivipansel is being investigated for treatment of vaso-occlusive crisis in SCD. Pfizer is also investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. Neither of these drugs is yet to market, neither will be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p> <p>Dr. Strouse is also a site co-investigator on a clinical trial of GBT-440, funded by Global Blood Therapeutics. This potentially disease-modifying therapy for SCD is not yet to market and will not be specifically addressed in these guidelines; however, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for a disease-modifying therapy that might prevent disease complications including pain.</p>

Webb 2/22/18	No	Yes	Dr. Strouse reported divesting his previously owned Medtronic Stock.
Kunkle 10/26/18; Webb 11/6/18	No	Yes	Dr. Strouse reported on April 23, 2018, that he expects to do paid consulting for Global Blood Therapeutics. As noted above, this company could be indirectly affected by the guidelines.
Russell, Kunkle; 1/6/2020	No	Yes	See Part D above for new disclosures. On 1/13/2020, Dr. Strouse confirmed all information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Strouse’s specialty is hematology / pediatric hematology / oncology. In his clinical practice, he sees children and adults with SCD and routinely treats them for acute and chronic pain. He has presented about SCD pain treatment at grand rounds and lectures. In his leadership role on the Sickle Cell Adult Provider Network, he has organized symposiums about pain management for adults with SCD. The organization advocates for access to acute pain management, following guidelines of the National Heart, Lung and Blood Institute.



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

ASH Guideline Panel on Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain:

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made?

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate "current" or "ongoing.")

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don't know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don't know
- No
- Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don't know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution?

I do not anticipate that my work on this panel will generate a strong reaction from my peers within and outside my institution. However, should that happen, I have the support of my department and my supervisor at work, other parents of sickle cell patients in my network, and my family.

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain:

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 3/27/17; Pai 3/30/17; Kunkle 1/23/18; Lottenberg 1/28/18	No	No	
Russell, Kunkle 11/22/2019	No	No	On 11/11/2019, Ms. Yusuf confirmed all information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

--



ASH Guideline Panel Declaration of Interests Form

Part A. Direct Financial Interests in or Relationships With Companies

Employment

1. Are you currently or in the past 24 months have you been an employee of any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each employment relationship.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Equity

2. Do you currently or in the past 24 months have you had equity in any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions? Equity includes stock, stock options, and other ownership interests but excludes diversified mutual fund shares.

No

Yes, as described below:

Add rows as needed for each equity interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>
Vapogenix	Stock options		Indirect conflict. Vapogenix is developing a new class of non-narcotic analgesics for localized pain. Products in the pipeline include a rapidly acting topical analgesic, a product for chronic wound pain, and a product for chronic inflammatory pain. These products are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that explicitly or implicitly suggest a need for new treatments for SCD-related pain, such as pain from leg ulcers.

Patents, Royalties, and Other Intellectual Property

3. Do you currently or in the past 24 months have you owned patents for or received royalties from any intellectual property or product used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Add rows as needed for each patent or royalty interest.

<i>Company</i>	<i>Description</i>	<i>Date Divested</i>	<i>For ASH Internal Use</i>
Oxford Press	Book Royalties		Not a conflict. Oxford Press is not an affected company.

Personal Income or Other Direct Transfers of Value

4. Do you currently or in the past 24 months have you received any personal income or other direct transfers of value (e.g., honoraria, gifts, travel support, meeting registration, meals) from any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company.

Column 2 Describe the activity for which you received the income or other transfer of value, e.g., research, consultancy, speakers bureau involvement, service on an advisory committee or board, expert testimony.

Column 3 Indicate when the activity ended, if applicable. (If the activity has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each activity.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
Pfizer	Advisory Board		Direct conflict. Pfizer markets opioid pain medications (e.g., oxycodone). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
			<p>recommendations on the company is expected to be trivial. Nevertheless, this could be an important perceived conflict.</p> <p>Pfizer is also developing rivipansel for treatment of vaso-occlusive crisis in SCD and is investigating efficacy of the phosphodiesterase 9 inhibitor PF-04447943 to prevent vaso-occlusive crises. These drugs are not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that implicitly or explicitly identify a need for therapies to prevent or treat painful vaso-occlusive crises.</p>
Endo Pharmaceuticals	DSMB		<p>Direct conflict. Endo Pharmaceuticals markets opioid pain medications (e.g., oxycodone and acetaminophen). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on</p>

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>
			the company is expected to be trivial. Nevertheless, this could be an important perceived conflict.
Pfizer	DSMB	May 2016	Ended before appointment.
Collegium Pharma	Advisory Board		Direct conflict. Collegium Pharmaceutical markets an extended-release formulation of oxycodone. These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Nevertheless, this could be an important perceived conflict.
Purdue Pharma	Advisory Board		Direct conflict. Purdue Pharma markets opioid pain medications (oxycodone, buprenorphine). These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial.

Company	Description	End Date	For ASH Internal Use
			Nevertheless, this could be an important perceived conflict.
Imara	Consultant		Indirect conflict. Imara is developing a disease-modifying therapy for SCD, IMR-687 (a selective phosphodiesterase-9 inhibitor). This product is not yet to market and will not be specifically addressed by these guidelines. However, the company could be indirectly affected by recommendations that explicitly or implicitly suggest a need for a disease-modifying therapy that might prevent disease complications including pain.
Vapogenix	Advisory Board		Indirect conflict. As described above under Question 2, Vapogenix could be indirectly affected by these guidelines.

My Partner’s or Spouse’s Interests

5. Currently or in the past 24 months has *your partner or spouse* had any of the interests or relationships described in questions 1-4?

No

Yes, as described below:

Add rows as needed for each interest.

<i>Company</i>	<i>Description</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Part B. Indirect Financial Interests in or Relationships With Companies

Industry-Funded Institutional Research

1. Through your institution, do you currently or in the past 24 months have you been involved in research funded or supported (e.g., in kind support, such as provision of a study drug) by any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the company funding or supporting the research.

Column 2 Briefly describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Company</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Paid and Volunteer Activities for Organizations Supported by Industry

2. Do you currently or in the past 24 months have you been involved in any volunteer or paid work for an organization that is wholly or partially funded by any for-profit company that develops, produces,

markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes, as described below:

Column 1 Name the organization. If known to you, describe any industry funding or support.

Column 2 Briefly describe your activity and role, e.g., employment, service on board of directors, other volunteer services.

Column 3 Indicate if your activity was paid or volunteered.

Column 4 Indicate when your involvement with the organization ended. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each organization.

<i>Organization</i>	<i>Description and role</i>	<i>Paid or Unpaid?</i>	<i>End Date</i>	<i>For ASH Internal Use</i>

Other

3. Do you have other indirect interests in or relationships with any for-profit company that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions?

No

Yes

If yes, please explain:

Part C. Relevant Other Interests That Are Not Mainly Financial

You have been invited by ASH to participate in the development of clinical practice guidelines on the following topic(s):

Sickle Cell Disease-Related Pain

The questions that follow are designed to elicit information about personal beliefs, intellectual positions or opinions, institutional relationships, and other interests that are not mainly financial and that may be relevant to guidelines on the above topic(s).

Personal Beliefs

1. Do you have strongly held beliefs related to the topic of these guidelines?

No

Yes

If yes, please explain: Believe sickle cell pain has a history of being poorly treated and actively engaged in improving treatment

Previously Published Opinions

2. Have you ever authored, coauthored, or publicly provided an opinion related to the topic of these guidelines, e.g., a clinical practice guideline, textbook, review article, meeting poster or presentation, grand rounds talk, letter to the editor?

No

Yes

If yes, what were those views and where were they made? Multiple see attached CV.

Non-Industry Supported Research

3. Currently or in the past 24 months, have you been involved in a leadership role in any research project not already reported under Part B, Question 1, relevant to the topic of these guidelines, e.g., a research project funded by a nonprofit or governmental organization?

- No
- Yes, as described below:

Column 1 Name the entity funding the research.

Column 2 Describe the research project.

Column 3 Describe your role: (a) national or overall principal investigator, (b) member of a steering committee of a study that does not have a principal investigator, (c) site or local investigator. If other than these options, please describe.

Column 4 Indicate when your involvement ended, if applicable. (If your involvement has not yet ended, indicate “current” or “ongoing.”)

Add rows as needed for each research project.

<i>Funder</i>	<i>Description of Research</i>	<i>My Role</i>	<i>End Date</i>
NIH	Pain coping	CO-I	2021
Donaghue Foundation	Web based ED pain guideline	PI	2017
CICATs	Functional pain evaluation	Co-PI	2017

Institutional Relationships

4. Could your salary be affected by recommendations on this topic?

- Don’t know
- No
- Yes

If yes, please explain:

5. Do you generate revenues for your institution or employer by clinical activity, teaching, speaking, consulting, testifying, writing, or otherwise sharing your knowledge or opinions about this guideline topic?

- Don’t know
- No
- Yes

If yes, please explain:

6. Could your institution benefit or be harmed by recommendations of guidelines on this topic?

Don’t know

No

Yes

If yes, please explain:

Career Advancement

7. How would you characterize the support you would receive from your primary mentor, institution, or other entities if your work on this panel or authorship of these guidelines generated a strong reaction from peers outside your institution? They would be strongly supportive

Involvement in Organizations With Relevant Policy Positions

8. Do you work for or are you a member of an organization with a stated position related to the topic of these guidelines, e.g., position statement, editorial, blog, amicus brief, or legislature or legal testimony?

No

Yes, as described below:

Column 1 Name the organization.

Column 2 Describe or reference any policy position of the organization that is related to the topic of these guidelines.

Column 3 Describe your role at the organization, including your involvement in deciding, promoting, or implementing relevant positions.

Add rows as needed for each organization.

<i>Organization</i>	<i>Relevant Policy Position</i>	<i>Your Role</i>

Clinical Practice

9. Do you see patients clinically?

No

Yes

If yes, what is your primary specialty or subspecialty?

Pediatric Pain Medicine

If yes, do you prescribe or otherwise recommend clinical interventions (e.g., screening or diagnostic tests, evaluations, treatments, procedures) that may be addressed by these guidelines?

No

Yes

If yes, please explain: Pharmacologic and non pharmacologic approaches

Expected Interests

10. Do you expect new financial or nonfinancial interests relevant to the topic of these guidelines not already declared in this form?

No

Yes

If yes, please describe:

Part D. New Declarations (ASH Internal Use)

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
n/a	"Two of my grants ended in 2017 and are no longer active."	1/18/18	OK, these are noted above as having end dates of 2017.
n/a	New mentoring grant from the Connecticut Institute for Clinical and Translational Science, due to run until 2020	1/18/18	Not a conflict
Endo Pharmaceuticals	Open Payments reports a payment for research on 1/17/2017.		Indirect conflict (payment was to Dr. Zempsky's institution).
Pfizer	Open Payments reports direct payments for consulting and other transfers of value (e.g., food and beverage, travel and lodging) during 2017 and 2018.		Direct conflict. Dr. Zempsky previously reported direct financial relationships with Pfizer.
Purdue Pharma	Dr. Zempsky disclosed that he is no longer a consultant for Purdue Pharma.	11/11/2019	
Imara	Dr. Zempsky disclosed that he is no longer a consultant for Imara.	11/11/2019	
GlaxoSmithKline	Dr. Zempsky is now a consultant for GSK.	11/11/2019	Direct conflict. GlaxoSmithKline markets opioids.
n/a	Funding from the Department of Defense to revise the ICanCope content to maximize the opportunity for clinical relevance for	11/11/2019	

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	individuals with neurofibromatosis. Dr. Zempsey is the co-investigator and the grant is expected to end July 2022.		
n/a	Funding from the Mayday Fund to evaluate workforce needs in pediatric pain medicine and create a curriculum for a broadened fellowship to increase pediatric pain providers nationwide. Dr. Zempsey is the PI and the grant is expected to end December 2020.	11/11/2019	
n/a	Funding from the National Institute of Arthritis and Musculoskeletal to test whether the Fibromyalgia Integrative Training program for Teens is more effective than cognitive-behavioral therapy alone or graded aerobic exercise alone, and whether treatment effects are sustainable over 1-year follow-up. Dr. Zempsey is the PI in a Multi-Site Randomized Clinical Trial of FIT Teens for Juvenile Fibromyalgia and the grant is expected to end March 2022.	11/11/2019	
n/a	Funding from the Connecticut Institute for Clinical and	11/11/2019	

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	<p>Translation Science (M1 Mentoring Program) to foster the development of investigators who are dedicated to improving the academic mentorship process. The program specifically focuses on the recruitment and mentorship of underrepresented students within all stages of the academic pipeline, from high school through to junior faculty. Dr. Zempsky is the PI and the grant is expected to end June 2020.</p>		
n/a	<p>Funding from the National Institutes of Health/National Institute of Child Health and Human Development to improve pain self-management and functioning in youth with sickle cell disease by developing and testing a tailored web and smartphone-based application. Dr. Zempsky is the co-investigator and the grant is expected to end in August 2021.</p>	11/11/2019	
n/a	<p>Funding from the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases</p>	11/11/2019	

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Internal Notes</i>
	(NIDDK) in a study on ‘Pain and Weight Treatment: Development and Trial of PAW’ to compare the effects of a cognitive behavioral intervention on youth with comorbid pain and obesity. Dr. Zempsky is the co-investigator and the grant is expected to end in March 2021.		
n/a	Dr. Zempsky disclosed that he is no longer a consultant for Purdue or Collegium and did not receive reimbursements from either company during the span of his time on the panel.	12/3/2019	
n/a	Dr. Zempsky disclosed that he is now a Global pain faculty member for GSK.	12/3/2019	

Part E. Summary (ASH Internal Use)

Name of guideline panel(s)	ASH Guideline Panel on Sickle Cell Disease-Related Pain
----------------------------	---------------------------------------------------------

Summary of ASH Judgments About Financial Conflicts

<i>Reviewer name and date</i>	<i>Direct Financial Conflicts?</i>	<i>Indirect Financial Conflicts?</i>	<i>Management Notes</i>
Webb 2/24/17; Panepinto 3/4/17; Kunkle 1/24/18; Lottenberg 1/28/18	Yes	Yes	<p>Dr. Zempsky receives direct payments from companies that market opioid pain medications, including Pfizer, Endo Pharmaceuticals, Collegium Pharmaceutical, and Purdue Pharma. These guidelines will offer recommendations about opioids. Because SCD is a rare disease, and because opioids are widely used for a variety of conditions, the impact of such recommendations on the company is expected to be trivial. Nevertheless, this could be an important perceived conflict. Recusal will be required. A majority of the guideline panel does not have the same or similar conflict.</p> <p>Dr. Zempsky also owns stock and receives direct payments from Vapogenix, which is developing a new class of non-narcotic analgesics for localized pain, and he receives direct payments from Imara, which is developing a disease-modifying therapy, and from Pfizer, which is developing drugs to prevent and treat vaso-occlusive crisis in patients with SCD. None of these pipeline products are yet to market, and none will be specifically addressed by these guidelines. However, the companies could be indirectly affected by recommendations that explicitly or implicitly suggest a need for these new therapies. These indirect conflicts will be managed by disclosure and by panel composition. Recusal will not be required.</p>
Kunkle 10/26/18; Webb 10/29/18	Yes	Yes	At the April 23, 2018, meeting of the guideline panel, Dr. Zempsky noted that in addition to opioids, Pfizer also markets non-opioid medications that have been studied and used for

			chronic pain management, including gabapentinoids and serotonin and norepinephrine reuptake inhibitors (SNRIs). Dr. Zempsky will be recused from making judgments about evidence or deciding recommendations addressing these medications (e.g., question 6).
Russell, Kunkle 11/25/19	Yes	Yes	New disclosures. See Part D above. On 1/13/2020, Dr. Zempsky confirmed all information on this form.

Summary of Direct Financial Conflicts

<i>Company</i>	<i>Description</i>	<i>Disclosure Date</i>	<i>ASH Notes</i>

Other Notes

Dr. Zempsky is a specialist in pediatric pain medicine. In his clinical practice, he sees and treats patients with SCD using pharmacologic and nonpharmacologic approaches. He is a co-investigator on research about pain coping funded by the National Institutes of Health, and he was recently a principal investigator on research about a Web-based emergency department pain guideline, funded by the Donaghue Foundation, and on research about a functional pain evaluation, funded by the Connecticut Institute for Clinical and Translational Science. He has extensively published about pain in SCD.