

From: [Krause, Philip](#)
To: [Gruber, Marion](#); [Fink, Doran](#)
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Date: Tuesday, August 10, 2021 4:01:35 PM
Attachments: [image001.png](#)

It sounds like Peter thinks he has taken over all vaccine operations, not just the Pfizer BLA...

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 4:00 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call

Well, wrapping this up by Friday is certainly news to me and I guess, I can enjoy my Saturday rather than calling into that meeting as Saturday's call may not discuss this issue if ACIP does not meet. CBER IOD not informing us of communications with our sister agencies is really unsettling!

Marion

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 3:52 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: RE: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call

FWIW, I heard from the ACIP lead Sara Oliver just a few hours ago (this is how I get my news about goings-on at FDA) that Peter told Amanda Cohn he is aiming to have EUA amendments for 3rd doses of Pfizer and Moderna in IC populations wrapped up by Friday this week! She told me that if there will be a substantial delay beyond Friday (and we heard from Peter this morning that David Cho assessed CDC's initial proposal for a submission to be deficient), then ACIP may postpone their discussion so as not to get peoples' hopes up but then not be able to deliver.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 10, 2021 3:46 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: FW: [EXTERNAL] Invitation: Aug. 14th CDC/IDSA COVID-19 Clinician Call
Importance: High

I think I should not decline but it will be difficult to present a perspective as all of us agree that 3rd doses in IC persons make sense but that short if an IND or an approved BLA there is not a regulatory mechanism to allow for 3rd doses. Peter talked this am about amending the EUAs to include certain IC populations. I am afraid if I decline this invite, they will ask Peter and then all bets are off (again).

Marion

From: Wollins, Dana <dwillins@idsociety.org>