I sent the questions below to Jared Skllings about practice issues, especially with respect to CPGs. He responded in writing prior to our Board of Directors meeting at APA. I'm including the questions and responses below.

Questions from Division 39 (Responses in black)

1. Given the recent *Wit v. UBH* court decision, has any thought been given to re-evaluating having insurance executives on clinical guidelines committees? If not, why not? Does the Professional Practice office appreciate why many psychologists and members of the public would raise questions about the inclusion of individuals on a CPG process from a corporation that a judge found inappropriately denying services based on its guidelines?

All individuals selected to serve on guideline development panels (GDPs) or the Advisory Steering Committee are reviewed by the current ASC, the Board of Professional Affairs, and the Board of Scientific Affairs. The Board of Directors makes the appointments. Before serving, each individual completes a detailed disclosure of conflicts of interest (COI) that is reviewed by staff and the chair of the ASC before the person begins serving. At the person's first meeting (in person or via teleconference), disclosure of COI occurs as well as at all face-to-face meetings and in annual written updates.

APA has thus far chosen to not exclude individuals associated with payers from guidelines committees; to date this has included 2 individuals out of 65 total individuals who have served. One of these individuals served for some time on the depression GDP but rotated off due to other commitments before the panel finalized its guideline document (thus the individual is not included in the final guideline document as a panel member/author; rather they are thanked in the acknowledgments). The other individual recently completed her three-year term on the Advisory Steering Committee (ASC); consistent with the other ASC members, she made no decisions about treatment recommendations.

Payers are a reality of the healthcare landscape in the United States. The two individuals associated with commercial insurance companies involved in APA's initiative have contributed by providing an understanding of real-life application of guidelines and implications within the health care landscape. Other perspectives represented on the panels have included psychology (both researchers and clinicians), medicine (family, psychiatry, internal), social work, nutrition, and patients (community members). However, it should be noted that the ASC has been clear throughout the guideline development process that costs of treatment should not be a factor in the panel's decision-making about recommendations.

The ASC appreciates the sensitivity that some may have regarding professionals associated with payers serving on the ASC or GDPs. The ASC has been satisfied that the COI disclosure process and strategies to manage conflicts has been sufficient. Although many organizations continue to focus their COI process on financial COIs, APA's process includes an extensive coverage of both financial and non-financial (e.g. intellectual) COIs that far exceeds that of many other organizations. Please refer to appended COI disclosure form for additional details.

The *Wit* decision was not about APA's CPGs, and APA would be concerned any time any entity inappropriately denied services.

2. The fact that most patients in the research studies actually do not achieve the kind of improvement that folks would be looking for or expecting in recommended treatments. Even in the improved conditions, most patients are still exhibiting symptoms and are not in remission. The [APA] marketing omits that the outcomes are underwhelming.

The systematic review underlying the PTSD CPG indicates generally large effects for many of the recommended psychological treatments and notes that there was insufficient evidence to be able to comment on remission as an outcome because most of the trials did not report on remission (as well as did not report on other outcomes relevant to quality of life). Here is what the review says about this:

"Effect sizes were generally large for the psychological treatments with moderate strength of evidence (SOE) supporting efficacy for improving PTSD symptoms (e.g., 28.9-point reduction in CAPS and Cohen's d 1.27 for exposure-based therapies), and numbers needed to treat (NNTs) were 4 or less to achieve one loss of PTSD diagnosis for cognitive processing therapy, CT, exposure, CBT mixed, and EMDR. Table 48 summarizes the main findings and SOE for the psychological treatments with evidence of efficacy. The outcomes included in the table are those most commonly reported: PTSD symptoms, loss of PTSD diagnosis, and depression symptoms.

Evidence was insufficient to determine efficacy for achieving remission (i.e. no longer having symptoms) for all psychological treatments except for CBT-mixed treatments (moderate SOE), because research trials typically did not report remission as an outcome. Similarly, evidence for improving other outcomes of interest—anxiety symptoms, quality of life, disability or functional impairment, or return to work or active duty—was generally insufficient (often with no trials reporting those outcomes). We noted a few exceptions: some evidence supported efficacy of CT for improving anxiety symptoms and disability (moderate SOE), efficacy of CBT-mixed treatments and brief eclectic psychotherapy for improving anxiety symptoms (low SOE), efficacy of CBT-mixed treatments for improving disability and functional impairment (low SOE), and efficacy of brief eclectic psychotherapy for improving return to work (low SOE)." (p. 135). Additionally, there is insufficient data to address outcomes nor remission from other kinds of interventions.

Unfortunately, this situation is common in clinical practice guidelines across healthcare. Ideally, future research will include greater focus on issues of clinical significance and outcomes such as quality of life that are important to patients. In striving to develop guidelines based on widely accepted practices in healthcare, APA is giving psychology a voice as a legitimate healthcare provider. Ultimately, guidelines represent the best available evidence to be used in conjunction with clinician expertise and patients' preferences, values, culture, and individual characteristics to maximize mental and behavioral health.

3. Exclusive reliance on RCTs without a thorough discussion of their limitations poses a number of problems as does the absence of evaluation of other methodologies. There is no real attempt to study patients who get better and why. Brief RCTs are expedient but do not address most of what is scientifically important. The PTSD Guideline lacks a coherent model of the underlying pathology. Thus, RCTs risk making superficially confident, but inappropriate, recommendations.

APA's clinical practice guidelines do not rely exclusively on RCTs. Decisions for each recommendation are based on four factors: 1) overall strength of the evidence, 2) balance of benefits versus potential harms/burdens of a treatment, 3) patients' values and preferences, and 4) applicability (generalizability) of the evidence. Sources of evidence used for each factor are as follows:

1) Overall strength of the evidence- overall quality of the evidence, rating depends on quality and type of evidence; rating is generally higher when good quality RCT data available and lower when RCT data is not available or of low quality.
2) Balance of benefits versus potential harms/burdens of a treatment - RCTs are used to determine efficacy and comparative effectiveness when evaluating benefits; a combination of observational studies, clinician and patient panel member input, and any available RCT data is used to evaluate potential harms/burdens of a treatment.
3) Patients' values and preferences – a combination of observational studies, clinician and patient panel member input, and any available RCT data (though RCT data are not usually available for this) are used to evaluate patients' values and preferences.
4) Applicability (i.e. generalizability of the evidence) - panel member judgment about the applicability of underlying evidence to the clinical target population based on PICOTS (population, intervention, comparators, outcome, timing, and setting).

It is worth noting again the diversity of identities and perspectives represented among panel members. Panel members across all three guideline panels have included psychology (both clinically focused and research focused), medicine (internal medicine, psychiatry, family medicine), social work, nutrition, and patient perspective (community members). Thus, a diversity of input was provided into the factors above for each recommendation.

Each clinical practice guideline produced by APA thus far has included a thorough discussion of the limitations of the guideline, which includes discussion of the limitations of the included trials/systematic reviews [Please note that the CPGs do not talk about limitations of using an RCT methodology per se broadly speaking, rather limitations of the included trials, etc.]. In fact, during the public comment period APA's guideline for the treatment of depression was critiqued for the large proportion of the guideline document that was devoted to discussing limitations.

Thus far, the questions addressed in APA's CPGs have been related to the efficacy of intervention, that is, what do we know about improvement when receiving a particular treatment. Panels have been very interested in understanding if outcomes differ by subgroups but in general, when data has been available, it has been insufficient to draw any conclusions. Please

note that the APA depression guideline (APA, 2019) states the following, which immediately precedes a section on the importance of individualizing treatments:

> "In reviewing the recommendation statements, the panel reminds the reader that a lack of evidence about a treatment does not imply that that treatment is not efficacious. Rather, there are several gaps in the literature about treatments as well as limitations in the specific literature reviewed by the panel due to methodological constraints, as discussed later in the guideline document. Clinicians are encouraged to provide informed consent to patients."

In many instances, subgroup analyses cannot even be conducted. For instance, the GDP for the overweight and obesity guideline, specifically asked questions regarding whether any patient or family characteristics moderated treatment efficacy, but they concluded that there was insufficient evidence to determine if any specific strategies were needed with patients or families having specific characteristics, and there was either no association or insufficient evidence to determine whether other population characteristics other than age were associated with outcomes. Panel members have had extensive discussions about this, and staff have provided such feedback to external systematic review teams. Panels are very invested in the question of who improves and why, but often rigorous data to addresses these questions does not exist.

This is one example of why evidence-based practice is critical - the clinician's expertise about other factors and ability to synthesize other research and data is necessary to guide decision making in real-world practice. APA's existing policy on evidence-based practice in psychology notes that the best available research evidence is to be used together with clinician expertise and patients' preferences, values, culture, and individual characteristics in making decisions about treatment. This policy is directly referenced in APA's depression guideline (APA, 2019) as follows:

> "Clinicians are encouraged to consider the report from the APA Presidential Task Force on Evidence-Based Practice (APA, 2006), Evidence-Based Practice in Psychology, which emphasizes the integration of best available research; patient characteristics, culture, and preferences; and clinical expertise for making treatment decisions."

Finally, different interventions are based on somewhat different models of the underlying pathology. The PTSD guideline panel strove to be inclusive of a wide range of treatments for PTSD (although data was ultimately insufficient to make a recommendation statement for all) and thus did not specify a particular model for the underlying pathology.

4. The emphasis on "brands" of therapy for the PTSD guideline process contradicts the APA (2013) Resolution on the Recognition of Psychotherapy Effectiveness passed by the CoR: "These large effects of psychotherapy are quite constant across most diagnostic conditions, with variations being more influenced by general severity than by particular diagnoses—that is, variations in outcome are more heavily influenced by patient characteristics for example, chronicity, complexity, social support, and intensity—and by clinician and context factors

than by particular diagnoses or specific treatment "brands" (pg. 102) (Beutler, 2009; Beutler & Malik, 2002a, 2002b; Malik & Beutler, 2002; Wampold, 2001).

This policy has applicability for general effectiveness of psychotherapy, and our science has evolved over the last 10-20 years since literature (as listed above) was published. At this point, we know that many different intervention approaches have positive outcomes for some conditions (see the recommendations for adult depression) but for other conditions, a more limited range of intervention approaches have demonstrated efficacy. Nearly all agree that clinician, context, and patient factors are all critical, and decisions regarding treatment selection add to the importance of these factors. They are not mutually exclusive; rather clinician and contextual factors should be integrated with informed decisions about the efficacy of interventions.

Also, regarding the quote in the question above, it might be true that variations in outcome are more heavily influenced by the above noted factors, but that does not mean that there is no influence by particular treatment packages/brands; in other words, they are not mutually exclusive. For comparable example, if exercise and healthy eating are the most determinative for Type 1 Diabetes outcomes, every patient should get those recommendations, AND it is still important to study whether insulin Medication A is better/worse than insulin Medication B.

In looking at the resolution (found here: https://www.apa.org/about/policy/resolution-psychotherapy), creating CPGs very much supports the resolution and in fact the resolution calls for this type of work. When you first click on the link above you'll see a reference to APA's CPG development (they call it treatment guidelines). In the 'therefore' section, it calls for APA to continue and further research on the efficacy and comparative effectiveness of psychotherapy as well as increase efforts to educate the public, integrate psychology into the health care system, etc. Here is the exact text:

"THEREFORE: *Be It Resolved that, as a healing practice and professional service, psychotherapy is effective and highly cost-effective. In controlled trials and in clinical practice, psychotherapy results in benefits that markedly exceed those experienced by individuals who need mental health services but do not receive psychotherapy. Consequently, psychotherapy should be included in the health care system as an established evidence-based practice.*

Be It Further Resolved that APA increase its efforts to educate the public about the effectiveness of psychotherapy; support advocacy efforts to enhance formal recognition of psychotherapy in the health care system; help ensure that policies will increase access to psychotherapy in the health care system, with particular attention on addressing the needs of underserved populations and encourage integration of research and practice; and support advocacy for funding.

Be It Further Resolved that APA encourages continued and further research on the comparative effectiveness and efficacy of psychotherapy."

5. The guideline over-emphasizes DSM diagnosis as if that would be sufficient for treatment planning. The entire guideline is a mapping of a manualized treatment

protocol onto a diagnosis. But psychologists fully recognize a lot more has to go into treatment planning than diagnosis.

Diagnosis is certainly not the only consideration in treatment planning. APA's evidence-based practice policy underscores that point, and it is the role of the autonomous clinician to integrate best available research (the research on efficacy can be found in relevant guidelines, and other research is informative as well) with clinician expertise and patient preferences and values.

APA's EBPP policy makes it clear that "having a cogent rationale for clinical strategies" is part of clinical expertise. It is incumbent upon the psychologist to document that rationale.

https://www.apa.org/practice/resources/evidence/evidence-based-report.pdf

Also, APA's next clinical practice guideline will focus on the treatment of chronic musculoskeletal pain, thus moving away from a guideline based on DSM diagnosis. Moreover, a working group is currently exploring the possibility of APA developing a transdiagnostic clinical practice guideline focused on emotion regulation. This group will be meeting in September 2019 to further explore this possibility. Understanding the limitations of mental and behavioral healthcare's current diagnostic framework has guided research on new paradigms for diagnosis – research in which many psychologists have been involved.

6. Has the [APA Practice] office considered whether there are liability issues raised for practicing psychologists now that many guidelines are being promulgated by APA? What guidance is it prepared to offer to psychologists for liability risk?

APA Practice organized a presentation on this topic at the Practice Leadership Conference in 2018. The primary message for any provider was to (a) document their decision-making and (b) assess and document outcomes.

APA attorneys and staff have developed an additional statement about the role and use of CPGs. It explains that CPGs are aspirational, and psychologists are not required to comply with CPG recommendations, nor that CPGs are the standard of care. Rather, CPGs are used by psychologists as tools, along with other resources and information, to facilitate decision making. The statement can be used by psychologists and/or their attorneys in the event of claims that a psychologist should be held liable for providing care in accordance with a CPG.

7. The PTSD guideline offers only brief, manualized treatments. When these become standards of care, the training of future psychologists becomes adversely affected. Such standards could work their way into accreditation guidelines and implementing regulations.

Current accreditation standards indicate that programs must integrate empirical evidence and practice. They state, "Practice is evidence-based, and evidence is practice-informed." These can

happen only to the extent that the research base is well developed. Currently, there is limited evidence that comes from routine practice and this is an area for which much more support is needed.

The current standards emphasize the need for discipline-specific knowledge and profession-wide competencies. Presently, it seems very unlikely that the accreditation standards will become so specific as to recommend any specific treatments. What the standards emphasize are broad exposures to graduate-level knowledge, as well as the skills to evaluate and learn from scientific findings. However, individuals may choose to specialize to learn specific treatments, though this by no means precludes the emphasis on broad foundational skills that are certain to remain part of accreditation standards.

General Comment:

It is noted that several of the comments and questions above pertain specifically to APA's (2017) clinical practice guideline for the treatment of PTSD. Many changes have been implemented in the short span of time since this guideline was released, and additional changes are in the planning stages as the guidelines continue to evolve. In June 2018 the Advisory Steering Committee (ASC) that oversees the initiative held an in-person meeting in Washington D.C. to discuss feedback received and make decisions about ways to be responsive to that feedback. A summary of that meeting can be found here: https://www.apa.org/about/offices/directorates/guidelines/2018-june-summary.pdf . By the time of this meeting, most of the work developing APA's most recent guideline on the treatment of depression had already been completed. However, the ASC and Guideline Development Panel for the treatment of depression strove to be as responsive as possible to that feedback, including the following changes in the depression guideline document compared to the PTSD guideline:

- Inclusion of a section on change processes/principles in therapy
- Larger discussion on the importance of the therapeutic relationship and related factors across therapies
- Broader discussion of the limitations
- Stronger call for future research in understudied areas and in understudied populations
- Discussion of the role of funding on the availability of research literature to be included in guidelines
- Discussion about adapting treatment to fit the individual
- Discussion about considering patients' diverse backgrounds, identities, and comorbidities
- Discussion on the implications of alignment with the Institute of Medicine standards
- Discussion on the need for testing moderators and mediators of treatment outcome

The ASC will be having another in-person meeting in Washington D.C. in September 2019. At this meeting the ASC will have further discussion about guideline methodology and future directions of the clinical practice guideline initiative. Liaisons from several APA governance groups will be present.