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Kelly at CCSAD: AA works, but most severe patients need treatment

On Sept. 6, as the remnants of Hurricane Dorian were heading for Cape Cod, the Cape Cod Symposium on Addictive Disorders’ (CCSAD’s) plenary speaker John F. Kelly, Ph.D., Elizabeth R. Spallin Professor of Psychiatry in the Field of Addiction Medicine at Harvard Medical School and the founder and director of the Recovery Research Institute, gave the 1,100 attendees — many of them representatives of the treatment field — some welcome news: 75% of people who once had a problem with drugs and alcohol are now in remission. “Think about that,” said Kelly, who has become a mainstay of the speaker circuit in the addiction field. “This disorder has a good prognosis, despite, sadly, the opioid crisis.”

Bottom Line…
AA works: That is the key message from the plenary speaker to CCSAD attendees this month.

The 75% finding came from the National Survey on Drug Use and Health (NSDUH), released in August (see ADAW, August 26). This was the first time the NSDUH asked this question.

“What other psychiatric disorder has a 75% remission rate?” he asked. As for the opioid crisis, Kelly also reminded the attendees of the significance of alcohol use disorders. “Don’t forget we see 100,000 deaths a year from alcohol,” he said. “But we are inured to that.”

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E-cigarette use under fire as officials struggle to pinpoint cause of illnesses

While federal authorities have not yet pinpointed a cause of more than 450 reported cases of serious lung illness and six deaths associated with use of electronic cigarettes, the notion among some addiction treatment professionals that e-cigarettes could serve as an optimal smoking-cessation strategy for their patients appears to be crumbling.

Bottom Line…
The Centers for Disease Control and Prevention maintains that no one chemical has yet emerged as the likely culprit in reports of more than 450 cases of lung illness and six deaths associated with vaping.

Shortly before ADAW went to press last week, Kansas health officials announced the sixth confirmed death nationally that has been linked to vaping. A Sept. 6 advisory from the Centers for Disease Control and Prevention (CDC) that the public should “consider not using e-cigarette products” while an investigation involving it, the Food and Drug Administration (FDA) and state and local officials is ongoing was followed last week by even stronger warnings from other health officials and from professional and advocacy organizations.

“It is time to stop vaping,” Lee Norman, secretary of the Kansas

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AA works

Kelly also noted that half of those 75% resolved their alcohol or drug problems without any external help — including without any help from mutual support groups like AA and NA. And for those who did get help, most used AA or NA, he said.

Most treatment programs have a “biased view” of the substance use disorder problem, because they only see the more severe cases who can’t resolve their problems on their own or with AA or NA. “People who resolved the problems on their own have less severe conditions, in terms of use, a lower density of pathology and higher recovery capital,” he said. “We don’t see those people.

In a forthcoming review to be published by Cochrane, Kelly and colleagues found that AA, using 12-Step Facilitation (TSF), does work. “You’re the first to hear this,” he told the CCSAD attendees at the Hyannis Resort and Conference Center. Using randomized controlled trials (RCTs) that were all manualized, the researchers compared studies using TSF to other treatments. “We found that AA does work and there’s strong evidence to support it,” he said, adding that treatments designed to support it, including follow-ups for up to three years, produce even higher rates of remission.

“AA and groups like it are the closest thing we have in public health to a free lunch,” said Kelly. “And we now know that these work.”

The Cochrane article, which Kelly said was going through its 18th layer of review at the time he spoke, found that AA confers benefit over time by mobilizing the same kinds of therapeutic mechanisms as “regular treatment,” said Kelly. “But it does so in the communities where people live,” he said. “And it’s a freebie.”

Perils of ‘brain disease’ label

It may not be beneficial to call addiction a chronic condition or a brain disease, in light of its high rate of remission even without treatment. “Talking about addiction as a chronic condition can be demoralizing,” said Kelly. People think, “I have this chronic brain disease, maybe I’ll never get well.” In addition, calling addiction a “brain disease,” which was hoped to reduce stigma, may do the opposite, he said. “Yes, genetic and biological explanations do help reduce stigma,” he said. “But in terms of social distance, it increases stigma.”

“[Examples of] social distance are whether you would have someone in recovery be a babysitter for you, have someone in a recovery be a roommate or let them marry into your family,” said Kelly. The phrases “chronic condition” and “brain disease” merely increase stigma.

“We need to talk about addiction as a treatable disease when we talk about it in biological terms,” Kelly said.

Kelly added that “people who call it a brain disease want to sell something,” acknowledging that this is an “unpopular opinion” (there were many booths in the CCSAD exhibit hall doing just this).

Remission rates

In support of treatment, Kelly pointed out, as he did at the NAATP conference (see ADAW, May 20), that it takes eight years and four or five treatment episodes to achieve one year of remission.
And remission is the word that should be used, he said. “In any other illness, like cancer, we’d talk about the remission rate,” he said. “But we focus on days of use or amount used.”

Kelly likes to focus on quality of life, and on functioning. Recovery is associated with improvements in both. But it shouldn’t take 15 years for the recovery sample in a recent study published in Alcoholism: Clinical and Experimental Research to have the same quality of life as the general population, as he has found. “That’s too long,” he said.

**Vulnerable early recovery**

Citing the “pink cloud period” that occurs in early recovery, Kelly noted that after six months, this goes away. “It’s the dawning of reality, and suddenly it hits them — the fog clears, they look at the future, they wonder how they’re going to make up for the lost time,” he said. This is a period of vulnerability in which the brain starts to clear, and there is more insight and more reflection, he said.

“We’ve been focused on that first 90 days. We need to get them to the one-year mark,” Kelly said. “That’s not the end, but the indices go up after the one-year mark.”

It’s still not popular to disclose recovery status, said Kelly: 25 million Americans have resolved a significant alcohol or drug problem, but only half of them identify as being in recovery. “Those with lesser problems who can stop without help don’t want to identify with that label,” he said. “They wanted to leave their prior history behind them.”

But it would be very helpful to find out how people did get into recovery. The smoking analogy may be useful. Smoking rates went down as prices went up, and smoking in public was not allowed. “This is price and availability,” said Kelly. “Do we see the same kinds of trends in the recovering population?”

Nicotine is the first drug people get addicted to, and it’s usually the last one to go, Kelly noted.

September is Recovery Month, and everyone refers to the phenomenon of recovery as a healthy change — but only half of the people it applies to want that label, said Kelly.

**ASAM involvement**

At this year’s CCSAD, the American Society of Addiction Medicine (ASAM) was more involved than ever, with many medical speakers and proponents of medication-assisted treatment.

At the end of the meeting, Hurricane Dorian had moved north toward Maine and the skies were blue, paving the way for the glorious late-summer conference to finish up with an ASAM day.

Stay tuned for more coverage. •

The $64,000 question — or however much money has been spent on naloxone, the lifesaving medication that rescues opioid overdose victims — is whether the distribution of the medication has an effect on overdose deaths.

It definitely has an effect on an individual — it saves his or her life. But in terms of overall rates, could other factors be responsible?

This will surely be the topic of scholarly evaluations months and years from now, when the money has been spent. In real time, some areas that have seen widespread distribution of naloxone have had reductions in OD deaths, but in others, these reductions aren’t apparent. Furthermore, it’s hard to know whether the link is causal. Naloxone rescues someone from an overdose, so it seems obvious that, of course, ODs would go down. But there could be other reasons for the decrease, which are important not to ignore if the public health focus is on the ODs and not just on naloxone.

We asked Harold Pollack, Ph.D., Helen Ross Professor at the University of Chicago School of Social Service Administration, to help decipher the issue.

“How does naloxone distribution relate to opioid overdose deaths?”

“**In any other illness, like cancer, we’d talk about the remission rate. But we focus on days of use or amount used…. We’ve been focused on that first 90 days. We need to get them to the one-year mark. That’s not the end, but the indices go up after the one-year mark.”**

John F. Kelly, Ph.D.
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reduce ODs. “Naloxone availability probably helped,” he said. “But you can’t fully prove these things.”

There’s also a difference between overdoses and fatal overdoses. Naloxone doesn’t prevent overdoses; it only prevents dying.

Pollack pointed to one initiative that has been shown to be successful in preventing deaths: pharmacists being able to give naloxone. “When you allow pharmacists to provide naloxone, you see a decline in fatal overdoses, but not a decline in nonfatal overdoses,” he said.

**Research**

Pollack, a rigorous researcher and critic, noted that certain papers have “methodological defects,” with a lot of triangulation — using different sources to validate data. “All of the papers have some of the same problems,” said Pollack. “When studies generate results, we do the best we can. We have epidemiological modeling of naloxone that suggests that it’s helpful.”

But he added that it’s too soon to fully understand what’s known about the recent decline in overdose deaths, partly because the circumstances are changing. Prescription opioids are no longer causing the majority of overdoses; heroin and illicit fentanyl are, for example.

“So many things are changing in the markets for prescription opioids and street drugs,” he said.

**Saving lives**

Whether naloxone is worth the money is beside the point, however. Of course it is, said Pollack. “Should we be distributing naloxone because there’s good reason to think it’s helpful and in an emergency it could be life-saving?” he said. “The answer is yes. Go with the best evidence and make sure people have access to naloxone.”

There are many things that can save lives, said Pollack. But to the person in front of you who is overdosing on opioids, naloxone is lifesaving. Statistical significance isn’t relevant, because it will always be significant in this case.

That doesn’t mean it isn’t important to find out more, because a public health benefit costs money and should bear the burden of proof, he said. “There are some downsides — you do not want cost to be a barrier to this,” he said.

Also, it’s critically important to know what is moving the needle, he said. “If getting naloxone from a pharmacy has a bigger impact than Good Samaritan laws, we want to know that,” he said.

It would also be valuable to know what happens after someone has an overdose event, he said.

**Closing pill mills**

“I don’t know how to make a time machine, but if we could turn back the clock, there’s a lot we would do differently,” said Pollack, adding that “overprescribing is a real issue.”

But the way it was handled — not making sure treatment was available — backfired. “Once this thing gets in motion, if you clamp down on prescribing, what really happens?” Pollack said. “We all agree that when a 19-year-old gets his wisdom teeth out, he doesn’t need a huge supply of Vicodin.”

But it gets tricky when it comes to the law enforcement–treatment connection, which wasn’t made in the prescription opioid clampdown. “You discover there’s a pill mill, and you close it down, and you say it would have been better if that pill mill didn’t exist, but what happens to the people who went there?”

Pollack said. “The person who’s responsible for shutting down the pill mill is not the same person as the person making sure treatment will be there.”

Furthermore, if your job is to identify people who are using their prescription authority to provide oxycodone, and you’re also not the person who’s running the state Medicaid program, not the person with the resources for treatment, then the prescription drug monitoring program will just identify patients who are likely addicted, cut them off from prescription opioids and send them to the street if treatment isn’t available.

**Hope**

The future isn’t completely bleak, said Pollack — with politicians, of all people, lining up to provide support. “I’ve never seen an issue in this space where there’s been such a bipartisan desire to help,” he told ADAW. “Like every issue, there’s a lot of grandstanding on both sides, but policymakers have a sense of urgency that is really admirable.” He compares this to the punitive approaches taken by politicians toward HIV and crack.

“We did a National Drug Abuse Treatment System Survey where we interviewed policymakers,” said Pollack. “It’s amazing how many legislators, including in the purple states, have a family member who was affected by the opioid epidemic.”

At one time, many people, said Pollack, were afraid there would be “Willie Horton” politics around the opioid crisis, referring to the

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“Should we be distributing naloxone because there’s good reason to think it’s helpful and in an emergency it could be life-saving? The answer is yes.”

Harold Pollack, Ph.D.
Naloxone competing for treatment dollars

Money is limited. If all of it goes to naloxone, what will be left for treatment? “I worry profoundly that we are going to screw up some issue that we are not even thinking about now,” Pollack said. “We are rewiring our addiction treatment system, and we’re not thinking about other issues, for which the opioid epidemic may not be the proper framing.”

For example, alcohol. “If I were in the alcohol space, I would be very nervous that things are not going to happen,” he said.

“We’ve expanded it in Medicaid, but there are many challenges, with things like Medicaid reimbursement rates easily neglected,” Pollack said. It’s easy to say a state expanded Medicaid, but if the customer isn’t “desirable” or the treatment provider doesn’t use proper treatment, this won’t work.

The Massachusetts example

Massachusetts is a unique scenario — it has been proactive and aggressive in science-based tools, but its opioid problems are still immense. “You often hear in discourse, ‘We know what to do, we just have to know how to do it,’” said Pollack. “Sometimes you do the best you can and you suffer a defeat,” said Pollack. “It’s not clear that they’re doing anything wrong. I think it’s a humbling example that we do the best we can. There’s no guarantee. The good thing about Massachusetts is, if they are missing an opportunity, they have a good opportunity to identify it and move forward on it.”

There are also many areas in a state — Boston is not the same as the rural Berkshires, where naloxone may be harder to come by. •

FDA: Avoid THC-containing vaping products

Last week, as respiratory illnesses linked to vaping spread, some resulting in deaths, the Food and Drug Administration on Sept. 6 issued an alert focusing on tetrahydrocannabinol (THC)-containing products (see story, page 1).

The FDA remains deeply concerned about these incidents and is working closely with the U.S. Centers for Disease Control and Prevention (CDC), as well as state and local public health partners, to investigate them as quickly as possible.

While the work by federal and state health officials to identify more information about the products used, where they were obtained, and what substances they contain is ongoing, the FDA is providing consumers with some information to help protect themselves.

In particular, many of the samples tested by the states or by the FDA as part of this ongoing investigation have been identified as vaping products containing THC, a psychoactive component of the marijuana plant, and further, most of those samples with THC tested also contained significant amounts of Vitamin E acetate. Vitamin E acetate is a substance present in topical consumer products or dietary supplements, but data are limited about its effects after inhalation.

While the FDA does not have enough data presently to conclude that Vitamin E acetate is the cause of the lung injury in these cases, the agency believes it is prudent to avoid inhaling this substance. Because consumers cannot be sure whether any THC vaping products may contain Vitamin E acetate, consumers are urged to avoid buying vaping products on the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores. Additionally, no youth should be using any vaping product, regardless of the substance.

At least one of the associated deaths that has been publicly disclosed appears to have been related to illicit THC vaping products. In many cases of illness reported by the states, patients have acknowledged recent use of THC-containing vaping products while speaking to health care personnel, or in follow-up interviews by health department staff.

It’s important to note that more information is needed to better understand whether there’s a relationship between any specific products or substances and the reported illnesses. To help gather and analyze as much information as possible, the FDA’s laboratory is working closely with its federal and state partners to identify the products or substances that may be causing the illnesses.

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The FDA is analyzing samples submitted by a number of states for the presence of a broad range of chemicals, including nicotine, THC, and other cannabinoids, along with cutting agents/diluents and other additives, pesticides, opioids, poisons, heavy metals, and toxins.

No one substance has been identified in all of the samples tested. Importantly, identifying any compounds that are present in the samples will be one piece of the puzzle but will not necessarily answer questions about what is causing these illnesses.

Federal and state partners are following any potential leads, including the presence of Vitamin E acetate found in many of the samples containing THC. The FDA is committed to taking appropriate actions as the facts emerge and keeping the public informed as it has more information to share.

Those who continue to use THC-containing vaping products should monitor themselves for symptoms (e.g., cough, shortness of breath, chest pain) and promptly seek medical attention if they have concerns about their health.

Those concerned about their health after using a vaping product can contact their health care provider or call the local poison control center at 1-800-222-1222. Health care providers also can contact their local poison control center.

The CDC and the FDA encourage the public to submit detailed reports of any unexpected tobacco- or e-cigarette-related health or product issues to the FDA via the online Safety Reporting Portal (https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx). •

For more information, go to www.fda.gov.

The other side: Pro-cannabis physicians dispute SG advisory

Last week (see ADAW, Sept. 9), we wrote about the advisory from U.S. Surgeon General Jerome Adams, M.D., recommending against marijuana use by pregnant women or adolescents (https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html).

Called “Marijuana Use and the Developing Brain,” the Aug. 29 advisory focused on those two populations, and noted that cannabis (marijuana) can act on cannabinoid receptors in the brain, which are critical to brain development. Lowering the perception of risk of use among young people, as well as suggesting that it can be used by pregnant women to treat morning sickness, is harmful to the teen and the fetus, said Adams.

He also said that no safe amount of marijuana use during pregnancy or adolescence has been established. It’s important for prevention campaigns and all messaging to be based on science, he said.

He noted that there are Food and Drug Administration-approved treatments for nausea, depression and pain during pregnancy that should be prescribed, and added that while further research is needed to understand the effects of marijuana on the developing brain, enough is known now to call for action.

But Adams’ advisory, which drew a “duh” reaction from many in the prevention and treatment field, was immediately challenged by cannabis advocates, including many M.D.s.

As we wrote last week: “Why demonize a drug that, if legal with quality control, is not as harmful as alcohol, for example? Could this backlash as a prevention message among, say, pediatric patients who decide not to discuss the matter with their doctors out of misplaced stigma?”

Benjamin Caplan, M.D., founder of the Boston-based CED Clinic, said that, indeed, for the most fragile patients, caution is essential. “But caution should reflect thoughtfulness,” said Caplan, who, with Peter Grinspoon, M.D., was our guide in last spring’s tour of Revolutionary Clinics, a medical dispensary near Boston (see ADAW, June 24).

“The full story of the effects on pregnancy, lactation and early development is still being explored,” Caplan told ADAW last week. “A careful examination of the medical literature and the unique circumstances of the individual patient” is what counts, he said, instead of “a blanket disregard for an entire natural pharmacy, simply out of misunderstanding, or a limited reading of the available data.”

There are dozens of inconclusive studies that don’t offer clear direction on reproducible harms of cannabis and pregnancy, said Caplan, citing three good-quality, long-term studies that show nontrivial (and nonpermanent) effects of cannabis on either pregnancy or the developing infant. “The apparent trend is that the less cannabis consumed, and the later during the pregnancy, the less risky it is,” he said. “On the other hand, it is important to realize that we do not have good-quality, long-term studies on the effects of many common human conditions on pregnancy and the developing fetus, including chronic stress, sleep deprivation, mood disorders, even hyperemesis gravidarum [morning sickness].”

“What the general public is demanding is an open-minded
Vaping from page 1
Department of Health and Environment, said, in announcing the sixth confirmed death, and first in his state, on Sept. 10.

“In light of increasing reports of e-cigarette associated lung illnesses across the country, the AMA urges the public to avoid the use of e-cigarette products,” American Medical Association (AMA) President Patrice Harris, M.D. said in a Sept. 9 statement.

Developments on this subject are largely happening on two tracks, both involving the FDA. While it is working with the CDC to test samples of vaping products used by individuals who have fallen ill, it also is ramping up pressure against industry practices that it believes have misled consumers.

On Sept. 9, the FDA issued a warning letter to industry leader JUUL Labs, stating that it has ignored a law that prohibits companies from marketing a modified-risk tobacco product without scientific evidence that the product poses less risk or is less harmful than conventional tobacco products. Among its ongoing concerns about JUUL, the FDA cites comments made by a company representative at a July congressional hearing, including that JUUL “was much safer than cigarettes” and “totally safe,” and that the FDA would approve it any day.

The federal agency has asked JUUL Labs to respond in writing to its concerns within 15 business days. For its part, the company says it will cooperate with the FDA’s requests, while insisting that its product is a safe alternative to smoking. JUUL Labs continues to point at reports among many illness victims that they had used e-cigarette products with Schedule I of the Controlled Substances Act, illegal under federal law for medical or recreational use. Let’s hope that Adams, who spearheaded a campaign to start syringe services programs in HIV-ravaged Scott County, Indiana, two years ago, in direct opposition to then-Governor Mike Pence (now vice president), has not been swayed by politics as surgeon general. His predecessor, Vivek Murthy, M.D., was ousted by President Trump in April 2017 (see ADAW, May 1, 2017).

“In light of increasing reports of e-cigarette associated lung illnesses across the country, the AMA urges the public to avoid the use of e-cigarette products.”

Patrice Harris, M.D., AMA

What is known

As of midweek last week, here are some of the key findings so far from an investigation that was launched in early August:

• More than 450 cases of lung illness associated with use of e-cigarette products were reported in 33 states and one U.S. territory as of Sept. 6, with the numbers likely to increase now that the CDC has worked closely with states to standardize the process for verifying and reporting cases. One death each in California, Illinois, Indiana, Kansas, Minnesota and Oregon has been confirmed since Sept. 10.

• Patients who sought treatment had experienced respiratory symptoms, such as cough and shortness of breath, and, in some cases, gastrointestinal symptoms. Many patients have required outpatient treatment or hospitalization, with some needing supplemental oxygen or assisted ventilation.

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- e-cigarette products, including devices, liquids, refill pods and cartridges, have been used by patients who have become ill.
- Although the CDC acknowledges that many (but not all) of the patients reported vaping with liquids containing THC or other cannabinoids, the agency has generally pushed back against any notion in recent days that there is any leading culprit at this time.
- FDA Acting Commissioner Norman E. Sharpless acknowledged on Aug. 30 that “the specific substances within the e-cigarette products that cause illness are not known and could involve a variety of substances.” But the FDA also has issued consumer-focused information stating that because most of the THC-containing samples also contained significant amounts of vitamin E acetate (a substance that is also found in some skin products and dietary supplements), “the agency believes it is prudent to avoid inhaling this substance.”
- The state of New York is intensifying its own investigation into makers of vaping products, and Gov. Andrew Cuomo last week issued an emergency order that will require warning signs at retail locations selling the products and will include a public service campaign on the risks of e-cigarette use.
- The CDC has said that while the investigation continues, people should consider not using these products, and if they do continue to use the products, they should seek prompt medical attention for any health concerns. Moreover, the agency says that no youths, young adults, pregnant women or nonsmokers should ever use e-cigarettes, and users should not buy products off the street or mix them with substances not intended by the manufacturer.

**Numerous unanswered questions**

Several questions related to this investigation and the use of these products remained unanswered last week, including:

- Is it possible that the investigation will not find one common chemical involved in all of these illnesses, and that multiple causes are at work?
- What are the possible benefits and risks associated with a former smoker immediately ceasing use of e-cigarette products over concern about this illness outbreak?

- Is the evidence that has emerged so far compelling enough to justify stronger actions from federal authorities, from more strongly worded warnings to consumers to regulatory actions restricting or banning sales of vaping products?

Neither the CDC nor the FDA had additional comments to offer to *ADAW* by press time last week. In the meantime, President Trump ordered a ban on flavored e-cigarettes on Sept. 11.

**Coming up…**

The conference of The American Association for the Treatment of Opioid Dependence (this theme is “Out of the Shadows: Managing the Opioid Epidemic through the Continuum of Care,” will be held October 19-23 at Disney’s Coronado Springs Resort in Florida. For more information, go to https://www.eventscribe.com/2019/AATOD/

The Police, Treatment, and Community Collaborative (PTACC) 2nd Annual Conference on Deflection and Pre-Arrest Diversion will be held November 10-13 in Ponte Verda, Florida. For more information, go to https://csgjusticecenter.org/law-enforcement/announcements/second-annual-police-treatment-and-community-collaborative-training-conference/

**In case you haven’t heard…**

In the interests of mutual transparency… Andrew Kolodny, M.D., published a retrospective declaration of conflict of interest in the Sept. 4 issue of the *Journal of the American Medical Association* (https://www.ncbi.nlm.nih.gov/pubmed/31483441), referring to two articles written in 2017 and 2018 with former Centers for Disease Control and Prevention Director Thomas Frieden (https://www.ncbi.nlm.nih.gov/pubmed/29049522 and https://www.ncbi.nlm.nih.gov/pubmed/29677298). In this month’s clarification, he added the information about being “expert witness in malpractice cases involving opioid prescribing.” At first glance, this made it appear that, for the first time, Kolodny was disclosing his medical expert testimony against opioid pharmaceutical companies in massive lawsuits. He had already done so. We asked Ivan Oransky, M.D., co-founder of Retraction Watch and executive director of The Center For Scientific Integrity, for a comment. "The rules around conflict of interest are still in formation," Oransky said. But instead of "death by 1,000 cuts," with accusations flying, authors and journal editors should just make all possible conflicts clear at the start via the ICMJE form.

Kolodny, who has been paid to tackle opioid pharma and at the same time has advocated against opioid prescribing, “the agency had additional comments to offer to *ADAW* by press time last week. In the meantime, President Trump ordered a ban on flavored e-cigarettes on Sept. 11.”