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MEMORANDUM

April 7, 2025

TO: Rhode Island House Committee on Corporations

FROM: Mac Haddow, Senior Fellow on Public Policy
American Kratom Association

STATEMENT IN SUPPORT OF HB 5565: A bill to properly regulate kratom and kratom products, including compounds in the kratom plant, mitragynine and 7-hydroxymitragynine and to repeal the current scheduling of kratom in Rhode Island.

The American Kratom Association ("AKA") respectfully requests the committee to support HB 5565 that will replace the current scheduling of kratom with a regulatory scheme that assures Rhode Island residents will have access for safe kratom products that are safely formulated, properly labeled, and age restricted.

MITRAGYNINE AND 7-HYDROXYMITRAGYNINE, THE PRINCIPAL KRATOM COMPOUNDS, DO NOT MEET THE 8-FACTOR CRITERIA FOR SCHEDULING UNDER RHODE ISLAND'S CONTROLLED SUBSTANCES ACT

The criteria for scheduling under CHAPTER 21-28. UNIFORM CONTROLLED SUBSTANCES ACT, SECTION 21-28-2.01[1], matches the 8-Factor criteria in the federal Controlled Substances Act (CSA), Section 201 (c), [21 U.S.C. § 811 (c)].[2]

Federal CSA Scheduling Criteria	Rhode Island Scheduling Criteria
(1) Its actual or relative potential for abuse.	**(i)** Its actual or relative potential for abuse;
(2) Scientific evidence of its pharmacological effect, if known.	**(ii)** Scientific evidence of its pharmacological effect if known;
(3) The state of current scientific knowledge regarding the drug or other substance.	**(iii)** State of current scientific knowledge regarding the substance;
(4) Its history and current pattern of abuse.	**(iv)** Its history and current pattern of abuse;
(5) The scope, duration, and significance of abuse.	**(v)** The scope, duration, and significance of abuse;
(6) What, if any, risk there is to the public health.	**(vi)** What, if any, risk there is to the public health;

[1] https://law.justia.com/codes/rhode-island/title-21/chapter-21-28/article-ii/section-21-28-2-01/
[2] https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section811&num=0&edition=prelim

(7) Its psychic or physiological dependence liability. (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.	**(vii)** Its psychic or physiological dependence liability; **(viii)** Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The FDA has made three specific attempts to have kratom's constituents, mitragynine and 7-hydroxymitragynine, classified as Schedule I substances:

1) The FDA's initial recommendation to schedule kratom was published in the Federal Register on August 31, 2016,[3] following which the DEA officially withdrew the scheduling recommendation on October 17, 2016, based on questions raised about the validity of the FDA's evidence and safety data. The DEA then requested that the FDA expedite its scientific and medical evaluation and scheduling recommendation for these substances.[4]

2) The FDA then submitted a second scheduling recommendation for kratom on October 17, 2017 and, after a comprehensive review by the Assistant Secretary of Health (ASH) at the U.S. Department of Health and Human Services (HHS) of the FDA's 8-factor analysis on the alleged safety and addiction liability of kratom, the ASH formally withdrew FDA's recommendation from the DEA on August 18, 2018.[5] The reasons for the rescission are directly relevant to any consideration or decision to schedule kratom that relies in whole or in part on the evidence provided by FDA, and here are some excerpts from the ASH letter explaining why the FDA had failed to meet its burden of proof:

    - "This decision is based on many factors, in part on new data, and in part on the relative lack of evidence, combined with an unknown and potentially substantial risk to public health if these chemicals were scheduled at this time." (Page 1)
    - ". . . one recently published peer reviewed animal study indicated that mitragynine does not have abuse potential and actually reduced morphine intake." (Page 3)
    - "Furthermore, there is a significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule I . . ." (Page 3)

[3] https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into

[4] https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr1013.htm

[5] https://www.dropbox.com/s/ljo3rxvgn4em2ub/dhillon-8.16.2018-response-letter-from-ash-radm-giroir%282%29.pdf?dl=0

In response to criticism by former FDA Commissioner Gottlieb on his decision to rescind the FDA recommendation for scheduling of kratom's alkaloids, Dr. Giroir made the following statement:

"FDA doesn't schedule; it only recommends. **FDA's recommendation was rejected because of embarrassingly poor evidence and data, and a failure to consider overall public health**."[6] (***emphasis added***)

3) Finally, in 2021 the FDA made a recommendation to the UN Commission on Narcotic Drugs (UNCND) to schedule kratom internationally, submitting their best evidence and data to support their recommendation under a far less rigorous standard that is required under the CSA in the United States. The UNCND ordered a comprehensive review by the Expert Committee on Drug Dependence (ECDD) comprised of 12 independent international experts on addiction and safety of substances. In a unanimous decision on December 1, 2021, the ECDD declared there was "insufficient evidence" to recommend scheduling of kratom by the UNCND.[7]

On March 16, 2022, in a letter from HHS Secretary Becerra[8], the Secretary acknowledged "knowledge gaps" on kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

On December 29, 2022, President Biden signed the FY23 Omnibus bill[9] with kratom report language commending NIDA for funding studies on kratom that "may provide help for some Americans struggling with addictions, given its analgesic and less addictive properties as compared to opioids."

The reason kratom is not scheduled at the federal or international level is straightforward: The FDA has failed to meet its burden of proof to document the addiction liability, the state of the science on the pharmacological activity, and the public health impacts of scheduling kratom.

THE SCIENCE ON THE SAFETY OF KRATOM AND THE FDA'S CURRENT POSITION

While the FDA has previously maintained the position that kratom poses a danger to the public, the agency refused to participate in a Hearing ordered by a Federal Judge scheduled on February 8, 2024, in the Southern District of California to provide witnesses and documents to support FDA's claims that kratom is a dangerous substance. This case was initiated by the FDA against an importer who had falsely identified kratom raw materials on the shipping manifest documents which resulted in a guilty plea. In the sentencing phase of the case, the Judge

[6] https://twitter.com/DrGiroir/status/1395874443726102533
[7] Expert Comm. on Drug Dependance, Summary of Assessments, Findings, and Recommendations of the 44th ECDD (2021), available at https://cdn.who.int/media/docs/default-source/controlled-substances/44ecdd_unsg_annex1.pdf.
[8] https://kratomanswers.org/wp-content/uploads/2022/07/TAB-14-HHS-Becerra-Letter-Lee-and-Pocan.pdf
[9] https://www.whitehouse.gov/briefing-room/legislation/2022/12/29/bill-signed-h-r-2617/

wanted more information from the FDA on their claims on the danger of kratom. In an email from the Assistant U.S. Attorney[10] the following explanation was provided to the Court on why the FDA refused to participate in the Hearing:

> "They [FDA] have refused to provide us with witnesses or documents to support our position . . . The reason they gave was that **they have not yet made a determination regarding whether kratom is dangerous." (*emphasis added*)**

The reason for that change in FDA's position reportedly is because FDA has completed a Single Ascending Dose ("SAD") study on whether kratom can be safely consumed by humans, and an abstract of the results of that study were reported at the 3rd International Kratom Symposium in Orlando, Florida on February 16, 2024. This study concluded that "**kratom appears to be well tolerated in humans at all dose levels**."[11] (*emphasis added*)

This key finding cleared the solicitation by the FDA for proposals to conduct a Human Abuse Potential ("HAP") study to determine whether kratom use results in dependency or addiction, and the severity if indicated.[12] This study is expected to be completed in 3-4 years.

In the SAD study, the FDA found that only two human subjects of the 40 participants experienced nausea only after the consumption of 12 grams of kratom, 24 capsules, within 5-minutes. The response was the same for both the kratom cohort and the placebo cohort demonstrating the nausea was related to consuming a high volume of plant material in a 5-minute period. None of the subjects reached the study's "stopping criteria" that would have resulted in termination of the study, but the FDA stopped the study because it concluded that kratom is well tolerated even at extremely high levels.

FDA has the legal authority to take regulatory action against a manufacturer, distributor, or vendor of a food product that is adulterated under the standards set forth in the Food, Drug and Cosmetic Act. It may do so if a food product "bears or contains any poisonous or deleterious substance which may render it injurious to health, or the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling."[13] If FDA finds a food product adulterated, the Agency may take enforcement action against a kratom

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[10] *Case 3:23-cr-00179-TWR Filed 12/06/23 Page ID.1032 Exhibit 6; United States of America, Plaintiff, v. Nine2Five, LLC (1) Sebastian Guthery (2), Defendants*

[11] https://static1.squarespace.com/static/6508b3f79033221c2aa1ea17/t/675332c4b06fcf63861b48b4/1733505733435/Reissig+CPDD+2024_FINAL.pdf

[12] *https://grants.gov/search-results-detail/351644*

[13] This list is not an exhaustive list. 21 U.S.C. § 342; *Questions and Answers Regarding Mandatory Food Recalls*, FDA Guidance, November 2018, available at https://www.fda.gov/media/117429/download.

company through issuing Warning Letters, Untitled Letters, 483 Inspection Observations, and Recalls.[14]

FDA regulates a product based on its intended use as evidenced by the product's labeling and claims.[15] Kratom, like other products intended to be a food, dietary supplement, or cosmetic, do not require FDA approval.[16] FDA has acknowledged it "does not have premarket approval of food products."[17] Instead, FDA can approve certain ingredients before they are used in foods such as food or color additives.[18] As such, kratom that is intended to be a food, and not a food or color additive, is not a product that FDA approves.[19] Therefore, it can be legally marketed as such. In addition, when intended for use as a food, it is immaterial that kratom does not have any "approved uses," since food products are not "approved."[20]

Kratom can be lawfully marketed and sold as a food as defined in the Federal Food, Drug, and Cosmetic Act. FDA does not preapprove food products. Although FDA has taken enforcement action against kratom manufacturers and vendors whose products are intended to be used for other purposes such as an unapproved new drug, the Agency has never adequately established all kratom is adulterated under required rulemaking subject to public comment. To the contrary, kratom has been lawfully and safely consumed as a food by American consumers for decades. Millions of Americans eat or drink kratom every day to improve their well-being. Kratom can be legally sold under FDA's laws, rules, and guidance.

Much of the discussion on kratom among policy makers focuses on the webpage FDA has published, "FDA and Kratom" on its Internet site without notice to the public where the FDA determined in the webpage that all kratom—in raw leaf and processed, extract forms—is categorically adulterated under the FDCA and therefore not marketable anywhere in the United States.

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[14] *See generally Compliance & Enforcement (Food)*, FDA.gov, available at https://www.fda.gov/food/compliance-enforcement-food.

[15] *See Small Entity Compliance Guide on Structure/Function Claims,* 67 Fed. Reg. 1225, Jan. 9, 2002, available at https://www.federalregister.gov/documents/2002/01/09/02-451/small-entity-compliance-guide-structurefunction-claims-availability.

[16] Unlike those products, FDA requires premarket approval of drugs and many medical devices.

[17] *Is it really "FDA Approved?",* FDA.gov, January 2017, available at https://www.fda.gov/consumers/consumer-updates/it-really-fda approved#:~:text=FDA%20approves%20food%20additives%20in,to%20food%2C%20and%20color%20additives.

[18] *Id.*

[19] A food additive includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly … in its becoming a component or otherwise affecting the characteristics of any food." 21 C.F.R. § 570.3. Food means "articles used for food or drink for man." 21 U.S.C. § 321. Kratom does not meet an additive definition, because kratom is itself the food, not the additive.

[20] Although premarket approval is not required, food products are regulated by FDA. For example, manufacturers at a minimum must meet Good Manufacturing Practices, have proper labeling, and register as a food facility.

The FDA made a significant update on February 22, 2024, to its FDA and Kratom webpage where they now acknowledge previous characterizations and reports on kratom deaths needed to be corrected:

> "In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. However, in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear."[21]

Additionally, the FDA now acknowledges the potential for science to help understand both the safety and addiction liability where they now correctly viewed through the lens of product forms and intended use in the consumption of kratom products. This is a dramatic shift from the FDA's initial 2016 position where they were calling for a total ban. Here is the excerpt from the FDA and Kratom webpage on this issue:

> "If a new drug application (NDA) is submitted for kratom (or one of its components) to treat a specific medical condition, FDA will review the scientific data to determine if a drug product containing kratom (or its components) is safe and effective to treat that specific medical condition. Consistent with FDA's practice with unapproved substances, until the agency scientists can evaluate the safety and effectiveness of kratom (or its components) in the treatment of any medical conditions, FDA will continue to warn the public against the use of kratom for medical treatment. The agency will also continue to monitor emerging data trends to better understand the substance and its components."[22]

THE NATIONAL INSTITUTE ON DRUG ABUSE (NIDA) POSITION ON KRATOM

National Institute on Drug Abuse (NIDA) Director Nora Volkow has testified before Congress that kratom should not be banned but rather regulated appropriately and new research should be undertaken. NIDA currently has funded more than $100 million in grants for kratom research. NIDA researched the FDA claims that kratom caused deaths, and concluded those deaths were largely from polydrug use or adulterated kratom products.

NIDA Director Nora Volkow has offered two public statements on kratom's potential value in the battle against drug overdose deaths. The first was published in NIDA Director Dr. Nora Volkow' blog and offered the following assessment of kratom on January 24, 2020:[23]

> "Research published in June in ACS Central Science provided new insights while raising new questions about the drug kratom. Its active ingredient mitragynine

[21] https://www.fda.gov/news-events/public-health-focus/fda-and-kratom
[22] *Ibid*.
[23] https://www.drugabuse.gov/about-nida/noras-blog/2020/01/reviewing-nidas-2019-achievements-looking-to-future

> acts as a weak partial agonist at the mu-opioid receptor (MOR), but new findings by a team that included researchers at Columbia and Memorial Sloan-Kettering found that the drug's analgesic properties are significantly mediated by a metabolite produced when mitragynine is consumed orally, called 7-hydroxymitragynine. In mice, at least, this compound seems to provide analgesia but with fewer respiratory-depressing and reward-associated side effects than other opioids such as morphine. These findings point toward the potential of this drug in pain research as well as the need for further research on the pharmacology of kratom's constituents, their toxicity and potential value in the treatment of opioid use disorder (OUD)."

Then, Director Volkow testified before the US House of Representatives Appropriations Committee on May 25, 2022, and stated the following:

> "Kratom, most notably mitragynine, has many interesting properties that could be of value potentially as a medication for pain. Also, interestingly, they could hold value as a treatment for addiction […] it is important to actually do research on this substance."[24]

Researchers at Johns Hopkins University concluded that 87% of adult consumers using kratom to treat opioid dependence reported relief from withdrawal symptoms, and 35% replaced the opioid with kratom within a year. The researchers concluded that serious adverse events are uncommon even at high consumption rates.[25]

The NIDA message is that kratom is a harm reduction tool that should be available to consumers. The science on kratom speaks equally powerfully on its value for consumers, and the FDA's own research proves pure and unadulterated kratom is not dangerous to consumers.

CURRENT REGULATORY STATUS OF KRATOM

The FDA's recommendation to schedule kratom under the CSA has been rejected on two separate occasions. Kratom is legal for sale in all but six states, all of which enacted bans on kratom between 2015-2017 at the encouragement of the FDA based on the claim kratom would be scheduled under the CSA, which did not occur. Fourteen states have now passed legislation known as the "Kratom Consumer Protection Act ("KCPA")" setting product standards to ensure kratom products are not adulterated and limiting sales to minors: Utah, Georgia, Arizona, Nevada, Oregon, Colorado, Oklahoma, West Virginia, Virginia, Florida, Kentucky, Maryland, Texas, and South Dakota.

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[24] https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health

[25] https://www.dropbox.com/s/bob9xr5jp2bwcg1/Garcia%20Drug%20and%20Alcohol%20Dependence%20kratom%20study%20Feb%203%202020%20.pdf?dl=0

Today, kratom is legal for sale in every other state.

The Federal Kratom Consumer Protection Act ("KCPA")[26], sponsored by Senator Mike Lee (R-UT), Senator Corey Booker (D-NJ), Congressman Mark Pocan (D-WI), and Congressman Jack Bergman (R-MI), will require the FDA to develop appropriate regulatory standards for the manufacturing and marketing of kratom products to consumers.

THE DEA'S DESIGNATION AS A DRUG OF CONCERN

The DEA designated kratom as a drug of concern following the rejection of the recommendation by the FDA to classify kratom as a Schedule I substance in 2016. That designation is appropriate for the role the DEA plays in monitoring substances of concern in the United States.

It is important to note the DEA has never designated kratom in any of its National Drug Threat Assessment ("NDTA") reports.

The NDTA is a comprehensive strategic assessment of the threat posed to the United States by domestic and international drug trafficking and the abuse of both licit and illicit drugs. The report combines federal, state, local, and tribal law enforcement reporting; public health data; open-source reporting; and intelligence from other government agencies to determine which substances and criminal organizations represent the greatest threat to the United States.

Kratom does not now, nor has it ever, met the criteria for inclusion in the DEA's NDTA report.

Status of U.S. States that have banned kratom. Based on early recommendations by the FDA, six states banned kratom from 2012 to 2017: Alabama, Arkansas, Wisconsin, Indiana, Vermont, and Rhode Island. Since then, five of those six states have begun the process of rescinding those bans and replacing them with a rational regulatory framework.

- Vermont followed the FDA's recommendation to schedule kratom in 2016. Pursuant to a petition filed with the Vermont Department of Health to remove mitragynine and 7-hydroxymitragynine from the Regulated Drug Rule, the Department granted the petition submitted by the AKA on March 1, 2023, and will commence rulemaking shortly to complete that process, stating as follows: "This email it to apprise you that the Department is granting your petition to remove mitragynine and 7-hydroxymitragynine form the Regulated Drug Rule." That rulemaking is currently ongoing.

- Wisconsin is another state that banned kratom on the recommendation of the FDA, and the Wisconsin Controlled Substances Board ("CSB") received a report from Dr.

[26] *Federal Kratom Consumer Protection Act (S. 3039 and H.R.5905)*

Chris Cunningham, Associate Professor of Pharmaceutical Sciences at Concordia University Wisconsin, with the following conclusion:

> "Based on our review of the available literature, we conclude that regulation of M. speciosa in Wisconsin as a schedule-I substance is not justified at this time. We base this conclusion, in part, on the scientific evidence demonstrating that M. speciosa and its chemical constituents have lower potential for overdose and abuse relative to other agents that are not scheduled in this way. We believe that controlling M. speciosa and its chemical constituents under schedule-I harms public health and stifles much-needed research into its therapeutic and toxic properties."

- In response, members of the Wisconsin Legislature asked the CSB for an assessment of whether kratom's constituents meet the statutory requirements for scheduling under the 8-factor analysis. On March 10, 2023, the CSB approved a motion to affirm mitragynine and 7 hydroxymitragynine do not meet the required 8-factors for scheduling under Wisconsin law.

- In Indiana, the House of Representatives took the first step to remove the kratom ban and enact the Kratom Consumer Protection Act in a vote of 54-30 on February 21, 2023. The bill is now under review with the Senate Health Committee.

- In Arkansas, where the Department of Health issued a ban on kratom in 2015, legislation to challenge the ban and replace it with the KCPA has been filed. On April 1, 2025, the Senate Committee on Public Health voted unanimously to recommend "do pass" that would repeal the current ban and adopt the KCPA.

The Position of the U.S. Congress on Kratom:

First, please consider the views of Representative Jack Bergman (R-MICH.) that he expressed in an Op-Ed piece in The Hill on July 28, 2023[27] where he made the following point:

> "In their relentless campaign to get kratom reclassified as a dangerous drug, the FDA has relied on three fallacious and thoroughly debunked objections to its widespread use: that kratom is unsafe, that it is highly addictive, and that it has no approved medical use. Even former HHS Assistant Secretary for Health Brett Giroir felt compelled to call out the FDA for relying on "disappointingly poor evidence and data and a failure to consider the overall public health" in coming to such a baseless conclusion. It is rare for a top-ranking HHS official to criticize the FDA for biased, shoddy work, but in this case the unsupported conclusions

[27] https://thehill.com/opinion/congress-blog/4125241-lets-prevent-the-feds-from-jeopardizing-veteran-addiction-recovery/

were so egregious that Giroir felt it necessary to publicly criticize them. Likewise, current HHS Secretary Xavier Becerra acknowledged substantial "knowledge gaps" regarding kratom and that "kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances."

Congress itself spoke clearly in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, FY2022, in its Report approved on July 15, 2021[28] including the following positions on kratom:

PAGE 134:

Kratom. — The Committee recognizes that NIDA-funded research has contributed to the continued understanding of the health impacts of kratom, including its constituent compounds, mitragynine and 7-hydroxymitragynine. The Committee is aware of the potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids and of research investigating the use of kratom's constituent compounds for opioid use disorder. The Committee directs NIDA to continue to invest in this important research, especially considering the increase in overdose deaths during the COVID–19 pandemic.

PAGE 187:

Kratom. — The Committee directs the Secretary to maintain current Agency policy to not recommend that the substances mitragynine and 7-hydroxymitragynine, known as kratom, be permanently controlled in Schedule I of the Controlled Substances Act, either temporarily or permanently, until scientific research can sufficiently support such an action. The Committee encourages AHRQ to continue to fund research on natural products that are used by many to treat pain in place of opioids, including kratom. Given the wide availability and increased use of these substances, it is imperative to know more about potential risks or benefits, and whether they can have a role in finding new and effective non-opioid methods to treat pain. The Committee recommends an additional $3,000,000 for this research and directs AHRQ to make center based grants to address research which will lead to clinical trials in geographic regions which are among the hardest hit by the opioid crisis.

Background on kratom and its safety profile

[28] https://docs.house.gov/meetings/AP/AP00/20210715/113908/HMKP-117-AP00-20210715-SD003.pdf

Publicly available research documents that kratom has a long history of acceptably safe consumer use, and, when used as an alternative pain management therapy, kratom provides a far more favorable safety profile for consumers compared to more dangerously addictive and potentially deadly classical opioid medications. Current scientific research suggests that kratom provides some pain relief activity on the pain centers in the brain without the dangerous and potentially deadly respiratory suppression induced by classical opioid medications.

The existing science on kratom does not justify its scheduling under the CSA, nor for kratom to be added to any local or state Controlled Substances list that would effectively remove it from consumer access. Here are references to peer-reviewed, published scientific articles addressing the addiction and safety profile for use of kratom by consumers supporting the position that scheduling is not appropriate:

- Patterns of Kratom use and health impact in the US-Results from an online survey, Grundmann et al.[29]
- The abuse potential of kratom according the 8 factors of the controlled substances act: implications for regulation and research, Henningfield et al.[30]
- The medicinal chemistry and neuropharmacology of Kratom: A preliminary discussion of a promising medicinal plant and analysis of its potential for abuse, Grundmann and Kruegel[31]
- Kratom use and mental health: A systematic review, Swogger and Walsh[32]

These studies and other independent peer reviewed evaluations published in scientific and medical journals provide the profile of a substance that is largely used safely to the benefit of the estimated 20+ million Americans.

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[29] https://pubmed.ncbi.nlm.nih.gov/28521200/
[30] https://pubmed.ncbi.nlm.nih.gov/29273821/
[31] https://pubmed.ncbi.nlm.nih.gov/28830758/
[32] https://pubmed.ncbi.nlm.nih.gov/29248691/