



NAC Banned on Amazon, Threatened by FDA

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✓ Fact Checked

STORY AT-A-GLANCE

- › The U.S. Food and Drug Administration is suddenly cracking down on N-acetylcysteine (NAC), claiming it is excluded from the definition of a dietary supplement. As a result, Amazon has removed all listings featuring NAC-containing supplements
- › The trade group for the supplement industry, the Council for Responsible Nutrition, is challenging the FDA's position, calling it "legally invalid," and is urging its members to continue selling NAC supplements
- › NAC supplements have been sold for 57 years, and the FDA has never taken action against it – until now, when 16 clinical trials are investigating its usefulness against COVID-19
- › NAC is a precursor to reduced glutathione, which appears to play a crucial role in COVID-19. There's evidence glutathione deficiency may worsen COVID-19 severity
- › NAC inhibits expression of proinflammatory cytokines that can trigger a cytokine storm, improves T cell response, benefits a variety of lung problems, and inhibits the hypercoagulation that can result in stroke and/or blood clots that impair the ability to exchange oxygen in the lungs

N-acetylcysteine (NAC), a precursor to reduced glutathione, appears to play an important role in COVID-19. According to an April 2020 literature analysis,¹ [glutathione deficiency may be associated with COVID-19 severity](#), leading the author to conclude that NAC may be useful both for its prevention and treatment.

NAC has a long history of use as a poison control remedy for [acetaminophen poisoning](#) in the emergency room. It neutralizes the toxic effects of the drug by recharging glutathione, thereby preventing liver damage. But the idea that NAC can also be helpful against viral infections is not new. Previous studies^{2,3} have found it reduces viral replication of certain viruses, including the influenza virus.

In one such study,⁴ the number needed to treat (NNT) was 0.5, which means for every two people treated with NAC, one will be protected against symptomatic influenza. That's significantly better than [influenza vaccines](#), which have an NNV (number needed to vaccinate) of 71,⁵ meaning 71 people must be vaccinated to prevent a single case of confirmed influenza. It's even better than [vitamin D](#), which has an NNT of 33.⁶

Early At-Home Treatment Is Crucial

In the video above, MedCram producer and cofounder Kyle Allred interviews Dr. Roger Seheult, a pulmonologist who has been treating COVID-19 patients since the beginning of the pandemic in 2020, about strategies that can significantly reduce your need for hospitalization should you contract this infection.

Among those strategies is the use of NAC, which used to be readily available over the counter and online. Disturbingly, as more information is coming out about the usefulness of NAC, the U.S. Food and Drug Administration is now clamping down on sales.

Since the beginning of this pandemic, global and national health authorities have done everything in their power, it seems, to discourage and prevent people from accessing any treatment that competes with the COVID jab. This appears to be yet another shameful attempt to prevent patients from helping themselves and boost the risk of infections progressing into more serious cases.

Should you come down with symptoms of COVID-19, early treatment is crucial. Not

only can it significantly reduce the length of time that you're sick, early treatment will also minimize your risk of **long-hauler** syndrome. A summary of the treatment strategies Seheult reviews in more detail in the video is as follows:

- Monitor your oxygen saturation status using a pulse oximeter. If your oxygen saturation drops below 94% at rest, you should seek medical treatment. Below 90%, you are hypoxic and need supplemental oxygen
- Use vitamins and other immune-boosting supplements, including vitamins C and D, **quercetin**, **zinc** and NAC, and/or medications such as monoclonal antibodies
- Use immune-boosting strategies such as sleep (melatonin can be used if you're experiencing poor sleep) and raising your core temperature in a hot bath or **sauna**
- Prevent spread at home using ventilation, air filtration and isolation

Amazon Removes All NAC Products

May 6, 2021, Natural Products Insider reported⁷ that Amazon is removing all NAC products from the site, following warning letters being sent out by the FDA stating NAC cannot be lawfully marketed as a dietary supplement because it was first studied as a drug in 1963.⁸

Consequently, products containing the ingredient are excluded from the definition of a **dietary supplement** under section 201(ff)(3)(B)(i) of the Federal Food, Drug & Cosmetic Act (FDCA). The thing is, NAC has been sold as a supplement for 57 years, and the FDA never did a thing about it – until now, when more than a dozen studies are investigating its usefulness against COVID-19.

As reported by Natural Products Insider,⁹ there are at least 1,170 NAC-containing products in the National Institutes of Health's Dietary Supplement Label Database. The FDA suddenly put NAC in its crosshairs in July 2020, when it sent out warning letters to seven companies that marketed NAC as a remedy for hangovers.¹⁰

CRN's Legal Arguments as to Why FDA Is Wrong

In December 2020, the trade group for the supplement industry, the Council for Responsible Nutrition (CRN), challenged the FDA's position, calling it "legally invalid."¹¹ CRN argued that FDA records fail to prove that the FDCA section in question actually applies to NAC.

In response to a Freedom of Information Act (FOIA) request to the FDA for information proving NAC was investigated as a drug in 1963, all they received was a handwritten letter containing "what appears to be a handwritten approval date of 1963" for an inhaled drug. According to CRN:

"This handwritten notation raises a number of questions about the reliability of this record, not the least of which is whether the approval date was actually 1963 or sometime later, why was the approval data handwritten, when was the notation made, and who made it. This is not the type of document that should be regarded as authentic."

Moreover, an inhaled substance cannot be treated the same as an orally ingested product, hence the NAC drug approved in 1963, if valid, still would not apply to oral supplements. The FDA did approve an NAC drug for oral-only use in 2016, but by then dietary supplement companies had already been marketing NAC supplements for several decades, and therefore cannot be canceled by a new drug approval. As reported by Natural Products Insider:¹²

"FDA's interpretation of section 201(ff)(3)(B)(i) in the warning letters also conflicts with 'the presumption against statutory retroactivity,' according to CRN. Mister and Olsen highlighted 'a well-established canon of statutory interpretation that legislation shall not be read to have a retroactive effect on private rights unless Congress expresses a clear, unambiguous intent to the contrary.'

Section 201(ff)(3)(B)(i) was incorporated in the Dietary Supplement Health

and Education Act of 1994 (DSHEA), which went into effect on Oct. 25, 1994.

According to CRN, the exclusionary provision should be not be interpreted to apply to products containing articles approved as drugs before Oct. 25, 1994 because DSHEA's text and the provision's legislative history suggests 'Congress expressed no clear intent for this provision to have a retroactive effect.

Further, Congress created section 201(ff)(3)(B)(i) to protect commercial interests necessary to incentivize new drug development in the wake of DSHEA's enactment ...

A retroactive application of this section does nothing to incentivize new drug development because drugs and supplements that were both on the market prior to DSHEA's passage already co-existed and drug companies developed these products with no expectation of DSHEA's protections.'"

CRN further argued the FDA failed to sufficiently explain this sudden change in policy on NAC, thus "rendering it arbitrary and capricious." According to CRN, before the seven warning letters in July 2020, "it was FDA's longstanding policy to permit the marketing of dietary supplements containing NAC."

Even though the agency had reviewed more than 100 notifications' structure/function claims for NAC-containing supplements over the years, they never raised the drug exclusion clause. In one response to a petition for a qualified health claim, the FDA had even stated that NAC was considered a dietary supplement.

NAC Supplements Continue To Be Sold Elsewhere

Unfortunately, Amazon has apparently decided to side with the FDA, despite the ongoing legal controversy and, as of this writing, has already removed all NAC product listings. Since Amazon owns Whole Foods Market, NAC products may be removed from brick and mortar stores as well. But that doesn't mean you can't find

NAC elsewhere.

“The Natural Products Association (NPA) ... is advising its members to continue selling NAC-containing supplements,” Natural Products Insider writes.¹³ “FDA hasn’t taken final agency action on NAC, and there’s been debate on such issues as when NAC came to market as a drug ...

‘Like we’ve told our members, sell it direct,’ [NPA president and CEO Dan Fabricant] added. ‘Sell it through other vendors because it’s not an unlawful ingredient. This is by no way a closed chapter with FDA on NAC.’”

NAC in COVID-19 Treatment

As mentioned, the FDA’s timing is highly suspect, considering its inaction in previous years, and considering the many studies now looking at NAC in the treatment of COVID-19. At present, ClinicalTrials.gov lists 16 clinical studies underway or completed involving NAC against COVID-19.¹⁴ That’s five more than there were in November 2020.

This includes a still-ongoing Phase 2 trial looking at NAC in patients with **severe COVID-19**. As noted in the trial description:¹⁵

“Recent studies suggest that the virus that causes COVID-19 may work by suppressing the immune system, which is the body’s defense against infections and other diseases.

White blood cells called lymphocytes are an important part of this defense, but recently it was found that the number of lymphocytes in a COVID-19 patient’s blood goes down as the infection gets worse and goes up as a patient gets better. N-acetylcysteine has been shown to help increase the number of lymphocytes in the blood when a virus is responsible for lowering it.”

Another recently completed trial¹⁶ used inhaled vapor of NAC in combination with diclofenac sodium, menthol and methyl salicylate in patients with mild to moderate COVID-19.

“ Researchers have confirmed that in severe COVID-19 cases, cytokines such as interleukin-6 (IL6), interleukin-10 (IL10) and TNF- α are all elevated. Once they reach excessive levels, a cytokine storm develops, causing significant tissue damage. NAC may be able to inhibit this damaging cascade.”

While the findings have yet to be published, they determined that “after regular inhalation of vapor with above medication, oxygen saturation level increased in the study group 384.61% in the morning and 515.79% at night comparing the control group. Furthermore, patients of study group need to stay nearly 1 day less in hospital in comparison to control group.”

Glutathione Depletion Worsens COVID-19 Outcomes

Previous research¹⁷ has shown NAC inhibits the expression of proinflammatory cytokines in cells infected with highly pathogenic H5N1 influenza virus. Proinflammatory cytokines also play a crucial role in COVID-19 severity.

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In one 2020 paper,¹⁹ the authors describe the case of a COVID-19 patient that had glucose 6-phosphate dehydrogenase (G6PD) deficiency, a genetic disorder that can

lead to hemolytic anemia, a condition in which red blood cells are broken down faster than they are made.

G6PD deficiency has been shown to facilitate human coronavirus infection (such as the common cold) due to the fact that G6PD depletes **glutathione**, and some of these patients are also at increased risk of hemolytic anemia when given hydroxychloroquine. As noted in this paper:²⁰

“G6PD deficiency may especially predispose to hemolysis upon coronavirus disease-2019 (COVID-19) infection when employing pro-oxidant therapy. However, glutathione depletion is reversible by N-acetylcysteine (NAC) administration.

We describe a severe case of COVID-19 infection in a G6PD-deficient patient treated with hydroxychloroquine who benefited from intravenous (IV) NAC beyond reversal of hemolysis.

NAC blocked hemolysis and elevation of liver enzymes, C-reactive protein (CRP), and ferritin and allowed removal from respirator and veno-venous extracorporeal membrane oxygenator and full recovery of the G6PD-deficient patient.”

In addition to that G6PD-deficient patient, NAC was also given to nine other COVID-19 patients who were on respirators but did not have G6PD deficiency. In these patients, “NAC elicited clinical improvement and markedly reduced CRP in all patients and ferritin in 9/10 patients.” The authors hypothesize that NAC’s mechanism of action “may involve the blockade of viral infection and the ensuing cytokine storm.”²¹

That said, they point out that it’s difficult to discern whether these anti-inflammatory effects were specific to the use of NAC, as steroids and other anti-inflammatory drugs were sporadically used. Still, they believe NAC does have the ability to reduce inflammation in patients with COVID-19.

Additional Research Findings

Other papers have also been published describing how NAC can benefit COVID-19 patients, including the following:

- An October 2020 paper²² in Medical Hypotheses cited evidence that NAC helps improve redox status, “especially when under **oxidative stress**,” replenish glutathione stores, increase T cells, inhibit the NLRP3 inflammasome pathway and decrease plasma TNF- α .

“Mediation of the viral load could occur through NAC's ability to increase cellular redox status via maximizing the rate limiting step of glutathione synthesis, and thereby potentially decreasing the effects of virally induced oxidative stress and cell death,” the authors wrote, adding:

“We hypothesize that NAC could act as a potential therapeutic agent in the treatment of COVID-19 through a variety of potential mechanisms, including increasing glutathione, improving T cell response, and modulating inflammation. In this article, we present evidence to support the use of NAC as a potential therapeutic agent in the treatment of COVID-19.”

- Another August 2020 paper, “Rationale for the Use of N-acetylcysteine in Both Prevention and Adjuvant Therapy of COVID-19,” published in the FASEB Journal, also explained the many potential benefits of NAC:²³

“COVID-19 may cause pneumonia, acute respiratory distress syndrome, cardiovascular alterations, and multiple organ failure, which have been ascribed to a cytokine storm, a systemic inflammatory response, and an attack by the immune system. Moreover, an oxidative stress imbalance has been demonstrated to occur in COVID-19 patients.

NAC ... has been proposed not only as a mucolytic agent, but also as a preventive/therapeutic agent in a variety of disorders involving GSH

depletion and oxidative stress ... Thiols block the angiotensin-converting enzyme 2 thereby hampering penetration of SARS-CoV-2 into cells.

Based on a broad range of antioxidant and anti-inflammatory mechanisms ... the oral administration of NAC is likely to attenuate the risk of developing COVID-19, as it was previously demonstrated for influenza and influenza-like illnesses.

Moreover, high-dose intravenous NAC may be expected to play an adjuvant role in the treatment of severe COVID-19 cases and in the control of its lethal complications ... including pulmonary and cardiovascular adverse events."

- A more recent paper²⁴ published on the preprint server ChemRxiv.org, June 1, 2021, hypothesizes NAC may be used to perturb the spike protein by reducing its solvent accessible disulfide bond, "thereby disintegrating its structural architecture." By so doing, the virus loses its capacity to infect your cells.

Analyses have shown NAC causes a threefold weakening of the spike protein's binding affinity with the ACE2 receptor. Other experiments have shown NAC inhibited SARS-CoV-2 replication in VeroE6 cells by 54.3%. According to the authors, "Our observed results open avenues for exploring in vivo pharmacopreventive and therapeutic potential of NAC for COVID-19."

NAC Shown to Improve Variety of Lung-Related Problems

Studies have also demonstrated that NAC helps improve a variety of lung-related problems, including pneumonia and ARDS,²⁵ both of which are common characteristics of COVID-19. For example:

Research²⁶ published in 2018 found NAC reduces oxidative and inflammatory damage in patients with community-acquired pneumonia.

Another 2018 study²⁷ found NAC improves post-operative lung function in patients undergoing liver transplantation.

A 2017 meta-analysis²⁸ found a significant reduction in ICU stays among ARDS patients treated with NAC (although there was no significant difference in short-term mortality risk).

A 2007 study²⁹ concluded NAC improves ARDS by “increasing intracellular glutathione and extracellular thiol molecules” along with general antioxidant effects.

A 1994 study³⁰ found NAC enhances recovery from acute lung injury, significantly regressing patients’ lung injury score during the first 10 days of treatment, and significantly reducing the need for ventilation. After three days of treatment, only 17% of those receiving NAC needed ventilation, compared to 48% in the placebo group.

NAC is also a well-known mucolytic used to help clear mucus out of the airways of cystic fibrosis patients.³¹ Some studies also suggest NAC can help reduce symptoms of COPD and prevent exacerbation of the condition.³²

NAC Also Protects Against Blood Clots

Lastly, NAC may also protect against hypercoagulation that can result in stroke and/or blood clots³³ that impair the ability to exchange oxygen in the lungs. Many **COVID-19 patients experience serious blood clots**, and NAC counteracts hypercoagulation,^{34,35,36} as it has both anticoagulant and platelet-inhibiting properties.³⁷

A 2017 paper³⁸ also found NAC has potent thrombolytic effects, meaning it breaks down blood clots once they’ve formed. This is largely thanks to the sulfur in NAC

(from cysteine). The sulfur reduces the intrachain disulfide bonds by von Willebrand factors that have polymerized by dissociating the sulfur bonds holding them together, thus contributing to the clot.

Once von Willebrand factor sulfur bonds are broken, the clots start to dissolve and the blood vessels open up again allowing for exchange of oxygen and carbon dioxide. According to the authors,³⁹ “NAC is an effective and safe alternative to currently available antithrombotic agents to restore vessel patency after arterial occlusion.” (Restoring vessel patency means the blood vessel is now unobstructed so that blood can flow freely.)

Two additional papers^{40,41} show the same thing. Importantly, NAC’s mechanism of action does not appear to increase bleeding disorders like heparin does, so it would likely be a safer alternative to the heparin used in the [MATH+ protocol](#).