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New Laws Allow Pharma to Make All Decisions for Patients

Analysis by Dr. Joseph Mercola Fact Checked | February 04, 2023

STORY AT-A-GLANCE

- The 2023 omnibus appropriations bill includes 19 lines that could give the U.S. Food and Drug Administration the power to ban off-label use of approved medications
- If the little-noticed provision is passed, doctors' ability to freely treat patients, and patients' ability to use all available treatments after making an informed decision, will be lost
- The amendment puts the FDA, and by proxy Big Pharma, at the helm of powerful health care decisions that should be made on an individual, personalized level between a patient and their health care provider
- In California, law AB 2098, which went into effect January 1, 2023, gives the state power to take away doctors' medical licenses if they spread "misinformation" that goes against the standard COVID-19 rhetoric
- The trend to allow a Pharma-controlled government to silence your doctor and dictate basic components of your medical care is not confined to the U.S. — it's happening globally

In the U.S., 1 in 5 prescriptions is written for an off-label use.[1] While sometimes this allows medications to be overused or misused, it also protects doctors' ability to freely treat patients, and patients' ability to use all available treatments after making an informed decision.

That 20% of medications are used off-label also indicates "a degree of freedom physicians currently have that will be foreclosed," notes English comedian and actor Russell Brand,[2] if a little-noticed provision in the omnibus spending bill is passed. "Literally, this will mean that your doctor will not be able to do what's best for you because they'll work for Big Pharma now," Brand says.[3]

19 Lines in 4,155-Page Bill Could Change Practice of Medicine

The 2023 omnibus appropriations bill — a 4,155-page tome involving $1.7 trillion in spending — includes 19 lines that could give the U.S. Food and Drug Administration the power to ban off-label use of approved medications. In a commentary for The Wall Street Journal, Dr. Joel Zinberg wrote:[4]

> *"Physicians routinely prescribe drugs and employ medical devices that are approved and labeled by the Food and Drug Administration for a particular use. Yet sometimes physicians discern other beneficial uses for these technologies, which they prescribe for their patients without specific official sanction.*
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> *The new legislation amends the Food, Drug and Cosmetic Act, or FDCA, to give the FDA the authority to ban some of these off-label uses of otherwise approved products. This unwarranted intrusion into the physician-patient relationship threatens to undermine medical innovation and patient care."*

FDA Wants Power to Regulate Practice of Medicine

"The new provision was enacted at the FDA's urging," Zinberg says,[5] in response to a 2021 legal ruling that limited the FDA's power to meddle with the practice of medicine. In March 2020, the FDA banned the use of electric shock devices for particular uses, namely to treat patients engaging in self-harm or aggressive behaviors that could harm others.

The devices are FDA approved, and while the FDA banned their use for certain contexts, it still allowed them to be used for smoking addiction and other purposes.[6] This led to a

lawsuit — Judge Rotenberg Education Center v. FDA — in which the Judge Rotenberg Education Center, a school for people with severe behavioral and intellectual conditions, sued the FDA over the ban.

The court ruled in the school's favor, stating that the FDA's ban violated federal law because it interfered with health care practitioners' authority to practice medicine. As it stands, the FDA does not have the power to ban medical devices for a particular use.

The school's attorney, Mike Flammia, who also represented students' parents in favor of the device's use, told CNN the decision "protects what all of us cherish, and that is the ability to go to our doctor and have our doctor decide what is the best treatment."[7]

As it stands, Section 360f of the FDCA[8] only gives the FDA authority to ban a medical device if it poses "an unreasonable and substantial risk of illness or injury." It can ban the device outright, but it can't pick and choose when it can and can't be used.

"Barring a practitioner from prescribing or using an otherwise approved device for a specific off-label indication would violate another FDCA section, which bars the FDA from regulating the 'practice of medicine,'" Zinberg says.[9] The FDA is trying to change that.

Pharma — Not Your Doctor — Would Dictate Medical Decisions

The omnibus amendment would change Section 360f so that the FDA could ban a medical device if it poses an unreasonable risk for "one or more intended uses" while leaving it approved for others. "Since the new provision lets the FDA skirt the ban on interfering with the practice of medicine by banning devices for particular uses, the agency will likely claim this as a precedent allowing it to ban off-label uses of drugs as well," according to Zinberg.[10]

This puts the FDA, and by proxy Big Pharma, at the helm of powerful health care decisions that should be made on an individual, personalized level between a patient and their health care provider.

Remember that in 1992, the Prescription Drug User Fee Act (PDUFA) was created, which allows the FDA to collect fees from the drug industry. "With the act, the FDA moved from a fully taxpayer funded entity to one supplemented by industry money," a BMJ article written by investigative journalist Maryanne Demasi explains.[11]

Now, significant portions of regulatory agencies' budgets come from the pharmaceutical industry that these agencies are supposed to regulate. In 1993, after PDUFA was passed, the FDA collected about $29 million in net PDUFA fees. This increased 30-fold — to $884 million — by 2016.[12]

It's also revealing that at the FDA, 9 out of 10 of its former commissioners between 2006 and 2019 went on to work for pharmaceutical companies.[13] As Brand noted:[14]

> *"What they're looking for is a crafty, sly, insidious way to be able to intercede in your relationship with your physician. And as usual, it's for your 'safety' and for your 'benefit' … Why would you want Big Pharma and a regulatory body that they fund interfering in your relationship with your doctor about your health?*
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> *Have they not found enough ways to extract revenue from you, to put your health second, to put your well-being way, way behind their profits and their list of priorities? Why is the bias moving even further in that direction? … This is not about medicine. This is about licensing. This is about profits, patents, the ability to extract revenue."*

Patients Suffer When Pharma's in Control

During the pandemic, it became clear how patients suffer when health agencies are allowed to dictate what medications doctors are allowed to prescribe to their patients. **Ivermectin** — a generic medication that doctors had success treating COVID-19 with early on — was quickly vilified, as were the doctors who attempted to prescribe it for COVID-19 patients.

In his book, "The War on Ivermectin: The Medicine That Saved Millions and Could Have Ended the COVID Pandemic," Dr. Pierre Kory details Big Pharma's suppression of this

drug when it was found to work against COVID-19. When he and colleagues first spoke out about the drug's potential, however, he was naïve. He said during our 2022 interview:[15]

> *"I worked a lot and I got deeply expert on ivermectin. But what happened in the next few months is that everything started going sideways, and I could not figure it out. I saw hit pieces … The thing is, I didn't know. I didn't know that what I was really doing — bringing forth data supporting the efficacy of a generic drug — that is poking the bear.*
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> *And when I say poking the bear, what is anathema to the pharmaceutical industry and their whole business model is they cannot have generic off-patent drugs become standard of care. It obliterates the market for their pricing new pills.*
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> *I didn't know I was stepping into a war. In the history of pharma, I don't think any single medicine threatened as many [drug] markets and campaigns. The only other medicine that did that was hydroxychloroquine, but they already killed hydroxychloroquine in 2020.*
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> *I was coming out now with ivermectin, and it threatened hundreds of billions of dollars in perpetuity for these insanely lethal vaccines, monoclonal antibodies, remdesivir, paxlovid, molnupiravir — all of the markets for their novel new pills to enter. I mean, I don't think any medicine has ever threatened that much of a market."*

'A Problem for Many Reasons'

If the FDA is allowed to ban medications for certain uses, we'll see more of what happened with ivermectin. It's a "problem for many reasons," Zinberg explains:[16]

> *"The statute gives the FDA the power, without any public input, to prevent patients' access to off-label therapies even though their physicians and their patients have found the treatments to be beneficial or even essential.*

… Allowing the FDA to ban certain off-label uses will impair clinical progress. Off-label use enables physicians to assess their patients' unique circumstances and use their own evolving scientific knowledge in deciding to try approved products for new indications.

If the treatment proves useful, formal studies are performed and published. If enough evidence accumulates, the treatment becomes the standard of care, even if the manufacturer didn't submit the product for a separate, lengthy and costly FDA review.

… Substituting regulators' wisdom for the cost-benefit judgment of physicians and their patients will discourage attempts to use approved products in new and beneficial ways and deprive patients of valuable treatments. Congress should reconsider this ill-advised legislation."

California Law Also Shackles Doctors' Freedoms

In California, regulators are also interfering with the practice of medicine. Law AB 2098, which was signed into law September 30, 2022[17] and went into effect January 1, 2023,[18] gives the state power to take away doctors' medical licenses if they spread "misinformation" that goes against the standard COVID-19 rhetoric.

Specifically, those who "disseminate or promote misinformation or disinformation related to COVID-19, including false or misleading information regarding the nature and risks of the virus, its prevention and treatment; and the development, safety, and effectiveness of COVID-19 vaccines" could be "disciplined," which includes loss of their medical license.[19]

It's akin to putting shackles on their wrists, forcing them to conform to a narrative intent on pushing dangerous gene therapies and ineffective medications. It's also a potential warning of darker things to come.

What constitutes "misinformation" or "disinformation" worthy of taking away a person's medical license? It's anyone's guess, really, but doctors afraid of being punished are

likely to steer clear of anything that could possibly fit under this definition — to the detriment of their patients.

Bill 2098 itself is packed with misinformation and ignores the scientific truths about COVID-19,[20] such as the fact that prior infection with COVID-19 results in natural immunity — immunity that's superior to that achieved via a COVID-19 shot.[21]

The bill, if it passes, will stop doctors from practicing medicine the way they deem best for the individual patient. It will also stop dissent — even when dissent is necessary and beneficial, and coming from people with expertise. And that's precisely the point.[22] In December 2022, Physicians for Informed Consent sued the state of California, arguing that AB 2098 violates the U.S. Constitution.

According to a news release, "The lawsuit argues that the State has weaponized the vague phrase 'misinformation,' thereby unconstitutionally targeting physicians who publicly disagree with the government's public health edicts on COVID-19."[23]

This Shift Isn't Just for the US

It's important to note that the trend to let a Pharma-controlled government silence your doctor and dictate basic components of your medical care is not confined to the U.S. — **it's happening globally**.

Proposed amendments to the 2005 International Health Regulations (IHR), for instance, aim to erase the concepts of human dignity, human rights and fundamental freedoms from the equation.[24] The first principle in Article 3 of the 2005 IHR states that health regulations shall be implemented "with full respect for the dignity, human rights and fundamental freedoms of persons." The amendment strikes that sentence.

Instead, international health regulations will be based on "principles of equity, inclusivity and coherence" only. This means they can force you to undergo whatever medical intervention they deem to be in the best interest of the collective.

Individuals won't matter. Human dignity will not be taken into consideration. Human rights will not be taken into consideration, and neither will the concept that human beings have fundamental freedoms that cannot be infringed. Autonomy over your body will be eliminated. You'll have no right to make personal health decisions.

While it may start slowly, such as with Pharma's quiet move to ban off-label usage of medications for certain uses, it will soon expand, chipping away at your sovereignty until it's gone. This is why it's imperative to share this knowledge and support measures that protect our human rights and individual freedoms.