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Epidemic

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Introduction

The U.S. opioid crisis began with the overprescription of pharmaceutical opioids like OxyContin; when users' prescriptions ran out, many turned to street heroin. Now, the crisis has entered its third wave, spurred by fentanyl. Though fentanyl was already a widely-used medical drug produced by legitimate pharmaceutical companies, illicitly-produced fentanyl is mainly abused today. This fentanyl is mostly made in China, and then sent directly to U.S. consumers through the mail, or funneled into the country by Mexican cartels.

China has been harshly criticized by U.S. political leaders for allowing large quantities of fentanyl, fentanyl analogues, fentanyl precursors and other new drugs known as Novel Psychoactive Substances (NPS) to be smuggled into America. Yet most of China's critics recognize the difficulty of controlling the country's vast chemical and pharmaceutical industries, where legal and illegal production can take place in the same facilities. Further, China has pledged strong action to stem the tide of these drugs. Earlier this year the country scheduled all fentanyl analogues, a move that was applauded by President Trump and others.

My deep reporting and research for my new book *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, however, shows that China has not been acting in good faith. The country's stated goal to crack down on these drugs has been undercut by its monetary policies, which directly support rogue Chinese chemical companies, the very same ones that are fueling America's opioid crisis.

Factors contributing to China's emergence as a global hub of illicit and counterfeit medicines and pharmaceuticals

A critical part of China's rapidly growing economy is its sprawling chemical industry. Its 400,000 chemical manufacturers and distributors (by U.S. Department of State estimates) span the country, making and selling everything from fertilizers to industrial solvents to antibiotics to psychoactive drugs. Most operate legally, some operate illegally, and others are in between. Driven in part by government subsidies and incentive programs, as well as a large population of skilled chemists, China's pharmaceutical industry has also been growing at a breakneck pace for decades, especially since the normalization of U.S.—China trade relations in 2000.

This chemical and pharmaceutical industry expansion has been driven in large part by exports, which are seen as critical to the country's continued growth. At the same time, China has been under fire for years for its record on food and medicine safety. Its medicines and supplements have been responsible for hundreds of deaths and thousands of hospitalizations around the world (exact numbers are unknown).

Reforms have been promised, but inspections remain sporadic and American officials have not been satisfied. For a variety of reasons, Chinese companies making medicines tend not to be inspected as thoroughly as those in Western countries. Though the U.S. FDA has a presence in China and is permitted to do some (though not all) of its desired inspections, it is, by all accounts, understaffed and underfunded.

Meanwhile, China's clumsy, understaffed bureaucracy has a difficult time controlling the country's chemical industry. Different layers of government are sometimes at odds with one another, local officials are corruptible, and industry regulations are confusing and poorly enforced. Thus, dodgy companies that keep their heads down can often operate without problems. Many have websites advertising legitimate products, while also making chemicals intended for illicit use.

"Lack of coordination and competing regulatory oversight...creates opportunities for some firms to hide unregulated activities in plain sight," testified the RAND Corporation's Bryce Pardo, an expert on drugs in China, to Congress in 2018.

While American chemical and pharmaceutical companies tend to portray themselves as focused and streamlined, many of their Chinese counterparts offer an extraordinary range of products. Regulating this industry—where chemicals that speed up rubber manufacturing and those combating erectile dysfunction are peddled by the same people—is complicated by the fact that China's chemical bureaucracy involves at least eight different agencies, including its Food and Drug Administration, Ministry of Chemical Industry, and General Administration of Quality Supervision, Inspection, and Quarantine.

Because there are so many regulatory agencies, and because so many chemical companies make both legitimate and illicit products, the Chinese government has a difficult time finding and penalizing those who break the law. "Many of China's chemical production facilities are described as 'semi-legitimate' producers, which are allowed to make chemicals but unlicensed to sell them to pharmaceutical companies," reads a 2016 report by Sean O'Connor of the U.S.– China Economic and Security Review Commission.

Being unlicensed doesn't necessarily stop these producers from selling to pharmaceutical companies, however. To further deceive the government, some companies set up "shadow factories," facilities shown to inspectors that are not actually where their drugs are made. Fentanyl-precursor manufacturers, for example, can evade scrutiny by labeling their products as industrial chemicals instead of pharmaceutical ones.

Few people seem to understand the laws governing the manufacture and sale of Chinese chemicals. Long and complicated ordinances are enacted at the whim of the central government, and then enforcement often falls to regional agencies, who may not fully understand what Beijing has commanded or may have their own, competing interests. Chemical companies manipulate the large amount of gray area to their own advantage to reap profits.

How the Chinese government supports its rogue chemical industry

For more than a decade, China has been encouraging its chemical and pharmaceutical industries by offering companies lucrative tax incentives, subsidies, and other direct financial support. The government has devoted enormous resources to the task, and these incentives have undoubtedly driven innovation and helped expand these industries and their exports. But the rise of fentanyls and NPS has been a terrible side effect. Quietly, money intended to spur legitimate innovation has gone to companies exporting deadly drugs that are killing tens of thousands of Americans annually. It's unclear how aware the Chinese central government is of this. Neither China's National Narcotics Control Commission, nor the Chinese embassy in Washington D.C., responded to my requests for comment.

One method the government uses to promote its chemical and pharmaceutical industries is by designating companies as New and High Technology Enterprises [NHTEs]. This is a critical designation toward receiving financial incentives. "Since China's new Enterprise Income Tax Law took effect in January 2008, the country's national and provincial governments have implemented a series of tax incentives for [NHTEs]," reads a briefing by the Asian business advisory firm Dezan Shira & Associates. "A hugely profitable industry in China, proactively applying for the different subsidies, tax exemptions and government funding schemes can significantly reduce a high tech company's tax burden and improve its market position."

It might seem strange to call these chemical and pharmaceutical companies "tech" companies, but the term tech is used differently in China. "It's not just those that make computers or chips or semiconductors," said Lucy Lu, research analyst for the Washington, DC–based Peterson Institute for International Economics. "If you're a chemical company and, say, invent some new chemicals or new drugs, you will be considered a tech company in China."

Other programs benefiting Chinese companies exporting illicit drugs include the Spark Program, which according to a Chinese government website is "aimed at popularizing modern technology in rural areas," as well as something called the Innovation Fund, both of which are administered by the Ministry of Science and Technology. This organization also administers the Torch Program, which helps these companies by assisting with marketing and personnel training, and in other areas. "In size, scale and commercial results China's Torch Program," wrote the Huffington Post, "is the most successful entrepreneurial program in the world. Of all the Chinese government programs, the Torch Program is the one program that kick-started Chinese high-tech innovation and start-ups."

The Torch Program also helps establish special industrial zones, which seek to promote Chinese businesses through subsidized land, subsidized rent, shared manufacturing infrastructure, and other resources. "China has been very generous in building these industrial parks as attractions for companies," said Gary Hufbauer, a trade expert at the Peterson Institute for International Economics. "It's a nice break, certainly on the land, and maybe even the building." The benefits of operating in these zones can significantly impact a company's bottom line. "The high-tech zones have become a major engine to China's economic growth," Zhang Zhihong, director of the Torch High Technology Industry Development Center, told China's state-run news agency Xinhua.

Many Chinese companies exporting dangerous drugs for illicit use are showered with government benefits. One particularly egregious example is Yuancheng Group, which is located in the city of Wuhan and sells huge quantities of fentanyl precursors. As shown in *Fentanyl, Inc.*, the government designated Yuancheng an NHTE in 2011, entitling it to preferential tax policies and also making it eligible for various rebates and reimbursements related to research-and-development efforts and staff training. Beginning in 2012 Yuancheng was sponsored for three years by the Torch Program, and has also been a beneficiary of the Spark Program and the Innovation Fund. It has also won government grants, and some of its sub-companies list an address in a special industrial zone. All of this has taken place while Yuancheng has been, by its own admission, selling fentanyl precursors all over the globe. Its clients include Mexican cartels, American drug dealers, and many others. This is perfectly legal under Chinese law; when one fentanyl precursor is banned in China, Yuancheng simply halts its sale and focuses on others that remain unscheduled.

Another company selling fentanyls and NPS that was incentivized by the Chinese government is 5A Pharmatech Co., led by Yan Xiaobing, a Chinese national who has been placed on the U.S. Justice Department's list of most prolific international drug traffickers. Indicted in September, 2017, Yan, who is also based in Wuhan, stands accused of conspiring to manufacture a host of NPS, including Flakka, N-bombs, synthetic cannabinoids, methylone, fentanyl and fentanyl analogues, and then distributing them in the United States and twenty other countries. China has

refused to extradite him to the U.S. 5A claimed to make legitimate chemicals for export, and to work with large firms including Johnson & Johnson and Pfizer, but representatives from both companies denied this. Nonetheless, 5A -- which is a subsidiary of Wuhan Livika Technology Co., and until early 2016 was known as 9W Pharmaceutical Technology Co. – had the support of the Chinese government. According to a company profile on Hubei Province's official website, the company was located in an economic development zone. (The company also claimed to have received certification as an NHTE, but this could not be confirmed.)

It is possible that Communist Party officials don't realize companies they support are exporting illicit fentanyl products and other NPS. Then again, it's possible that they do, considering that the Chinese tax code directly encourages these exports.

This practice apparently stems from China's desire to upgrade its pharmaceutical industry. While the US pharmaceutical industry makes expensive, patent-protected, brand-name drugs, China specializes in cheap generic drugs, which is why its legal, aboveboard chemical revenue is smaller than America's, despite greater output.

China is trying to change this, however. A countrywide initiative called "Made in China 2025" seeks to upgrade the country's manufacturing status, to move it up the "value chain," using policy changes and government investment. The Chinese pharmaceutical industry is a major part of this initiative, and the government has moved to incentivize increased spending on research and development, and to promote industry consolidation. The goal is to produce higher-quality, more expensive medical drugs, for use at home and abroad.

One way China works to expand these exports is by offering tax reimbursements via the value-added tax rebate, or VAT rebate. Companies are reimbursed for tax money they have already paid in the process of making their products—for example, taxes they paid when they bought the ingredients needed to make a certain chemical compound.

The VAT rebates go as high as 16 percent; a 16 percent rebate means the exporters receive a full tax reimbursement. Not every exported chemical gets one, but thousands do, and the rebates vary wildly. According to China's State Administration of Taxation website, aspirin and sildenafil (the drug in Viagra) get no VAT rebates. Melamine, the industrial chemical used to adulterate milk powder products that was linked to infant deaths in 2008—but which also has safe uses—gets a 10 percent rebate. So does fentanyl. And beyond that at least ten fentanyl analogues—including 3-methylfentanyl, which is not used for legitimate medical reasons, anywhere—get a 13 percent rebate. In September 2018, China announced it would raise VAT rebates on about four hundred different products for export, from chemicals to semiconductors, in what Reuters described as "a bid to boost prospects for shipments amid its trade war with the United States." Also in 2018, the VAT rebate for fentanyl was increased, from 9 percent to 10 percent. It was not

one of the four hundred products from the September announcement, and it is unclear when exactly in 2018 this occurred, or whether it was also in response to the trade war.

China began issuing VAT rebates in 1985. It doesn't explain why particular chemicals get the rebates they do; one possibility is that products with a "value add" get higher rebates, while generics get lower rebates or nothing. There is no doubt that if a particular chemical's VAT rebate rate is higher, companies are more likely to export it.

Among the beneficiaries of these rebates are legitimate Chinese companies legally manufacturing fentanyl for medical use. Only three types of fentanyls are legally permitted to be made in China for domestic medical use or export: fentanyl, sufentanil, and remifentanil. It's unclear why at least eight other fentanyl analogues get VAT rebates. And while it's also unclear how many Chinese companies exporting fentanyls or fentanyl precursors for illicit use are receiving these tax rebates, the CEO of Yuancheng Group, which exports fentanyl precursors that are used illicitly, says his company is included among them.

There is little doubt that China is undercutting its publicly stated goal of stopping the export of dangerous drugs for illicit use. Besides encouraging their export through its tax code and high-tech subsidies, it has been ineffective at ensuring such exports don't end up in the wrong hands.

"If China had a subsidy on lead, you'd probably see a lot more bullets coming out of China, and that's what's happening here with the precursors. They're just subsidizing whatever is a high-value commodity, and in this case it just happens to be really potent synthetic opioids or opioid precursors," said RAND's Bryce Pardo. "The Chinese government doesn't have a good capacity for regulating its own industry. At the same time, it wants to export and make as much money as possible. They're getting ahead of themselves and causing a lot of harm in the process."

Dr. Katherin Tobin, former Commissioner for U.S.–China Economic and Security Review Commission, said my findings fit with a pattern of Chinese government activities that the Commission has long been tracking.

"The primary incentive, particularly for local-level Chinese government officials, is to support economic growth," said Tobin. "Therefore, it is likely Chinese regulators and policymakers have chosen to look the other way regarding the production and export of fentanyl products. This incentive structure persists despite the Chinese government's repeated promises to crack down on narcotic flows, a sign that Beijing is guilty of gross negligence in enforcing its chemical regulations, bad faith in its negotiations with the United States, or both."

How to stem the flow of illicit synthetic opioids from China

The U.S. says stemming the flow of illicit synthetic opioids and other NPS from China is a top priority. U.S. Senators Chuck Schumer and Tom Cotton, who are targeting fentanyl produced in China, wrote recently in *USA Today* that legislation they proposed would "require the imposition of sanctions on criminal organizations that traffic these drugs into the United States, the financial institutions that assist them and the drug manufacturers that supply them. The legislation would also urge diplomatic efforts with U.S. partners to establish multilateral sanctions against foreign traffickers, and authorize new streams of funding across the U.S. government to combat opioid trafficking." It would also "allow the U.S. to apply pressure to the Chinese government to boost regulatory enforcement on pharmaceutical companies that create and distribute the drug."

Such actions could be beneficial in numerous ways, including potentially cutting into illicit drug manufacturers profits; I've found that these organizations sometimes stash money in American-owned banks or banks owned by countries with U.S. partnerships, for example.

Greater regulatory enforcement by China is also critical. President Xi Jinping has sought tighter regulations in drug production and increased penalties for rogue actors, and in March 2018 it was announced that the Chinese FDA was being reorganized to strengthen its oversight capabilities. But more action is needed.

A sticking point has been China's lag behind the U.S. in scheduling dangerous fentanyls and NPS, often for years. For this reason the U.S. lobbied China to "blanket ban" fentanyls, similar to America's Federal Analogue Act. Signed by President Reagan in 1986, this law specifically targeted fentanyls and NPS (then known as designer drugs) by making anything deemed "substantially similar" to schedule I or II psychoactive drugs—in either effect or structure—automatically illegal from the moment of creation. The effectiveness of this law has been debated; it is difficult to enforce, and some scientists say it inhibits their ability to do scientific research and develop effective new medicines.

But President Trump got his wish when, on May 1, 2019 China scheduled all fentanyl analogues, including those not yet created. This is the most far-reaching, and potentially significant, type of action China has taken in this realm. It is far from a panacea -- China has difficulty enforcing its drug laws -- and yet it may be effective, considering that, in the past, shortly after China schedules a specific chemical, U.S. seizures of that chemical drops, something that is not true when a chemical is scheduled in the U.S. or internationally. Further, a large percentage of the dangerous recreational chemicals made in China are synthesized not by cartels or criminal organizations, but by companies operating legally. The leaders of these organizations often follow the letter of the law.

The effectiveness of China's "blanket ban" of fentanyl analogues should be judged by the amount of seizures of novel fentanyls in the U.S. in the coming years. If the numbers drop

significantly, the blanket ban should be considered a success. However, even if China succeeds in substantially lowering its illicit NPS output, the industry may simply migrate to other countries, like India.

There is much more the U.S. can do to effectively stem the flow of illicit synthetic opioids and other NPS from China. My suggestions:

1) Pressure China to eliminate tax rebates, grants, and subsidies to companies exporting illicit fentanyls, fentanyl precursors, and NPS.

Beyond its illicit uses, fentanyl is an important medical drug. For this reason it is fine for legitimate Chinese companies to receive VAT rebates for exporting it and other chemicals used in medical settings. But it is outrageous that China offers these tax rebates for at least eight other fentanyls that are illegal for Chinese export, including chemicals that have never been used for legitimate medical reasons, anywhere.

And it's not just VAT rebates. As detailed above, Yuancheng and other companies selling fentanyls, fentanyl precursors, and NPS receive other subsidies and grants from the Chinese government, including from programs run by China's Ministry of Science and Technology. These are clear and obvious examples of China encouraging the production of dangerous drugs that are killing Americans, and the U.S. should pressure them to cease doing so.

2) Schedule more fentanyl precursors and pressure China to do the same.

Making fentanyl from scratch is a complicated process, but making it from precursors is a fairly simple one. Mexican cartels, for example, tend not to have access to trained chemists capable of making it from scratch, and thus tend to import the precursors from China.

Controlling the flow of fentanyl precursors, then, is of critical importance, and yet currently Chinese companies are able to export them to anyone for illicit use, with no controls whatsoever.

According to the DEA, there are sixteen different known precursor chemicals that can be used to make fentanyl. Only two are scheduled, NPP and 4-ANPP. The U.S. scheduled NPP in 2007, and 4-ANPP not long after, but they weren't scheduled in China until November, 2017, ten years later. As a result, when the current fentanyl crisis began to gain speed in the 2010s, Chinese companies were well-positioned for legal NPP and 4-ANPP sales, with virtually no oversight from the Chinese government.

To this day, the rest of the known fentanyl precursors remain unscheduled, not just in China but in the U.S. and worldwide. And so Chinese companies are able to sell them, for illicit use, with

no consequence. Since 2017, for example, Yuancheng Group has been pushing fentanyl precursors known as N-phenylpiperidine-4-amine and 4-anilino-1-benzylpiperidine. The company's salespeople offer to send these precursors in phony packaging to fool U.S. customs. - purporting to contain, say, banana snacks or dog food.

Much has been made over China's scheduling of fentanyl analogues, but their scheduling of fentanyl precursors could potentially have an even larger impact. They are unlikely to do so, however, unless the precursors are first scheduled in the U.S. and internationally.

3) Pressure China to allow the DEA and the FDA to do their work.

Sean O'Connor's 2017 U.S.—China Economic and Security Review Commission report noted "several recorded instances of Chinese law enforcement and drug regulators delaying visa approvals for FDA officials and deleting laboratory test records." The DEA is also sometimes not allowed to do its work in China. According to Katherine Tobin, former member of the U.S.—China Economic and Security Review Commission, China's pledge to control fentanyls are meaningless without enforcement. "The Chinese government's promises have not been fulfilled until U.S. officials and law enforcement on the ground in China—such as the DEA and FDA—observe these controls being implemented in a manner consistent with Beijing's pledge to crack down on flows of fentanyl, as well as fentanyl analogues and precursors."

It's not just the American agencies, however. China's own drugs- and medicine-regulating agencies need to be properly staffed and funded, before there can be any hope of consistent enforcement of China's drug laws.

4) Promote harm reduction at home

China believes the U.S. bears a great deal of responsibility for the opioid crisis, considering the overwhelming demand for opioids here. Indeed, predatory tactics by U.S. pharmaceutical companies and failed U.S. policies have helped create the world's largest market for opioids. Therefore, even if the above tactics are effective in diminishing China's export of illicit fentanyls and NPS, if American demand for these drugs does not subside, the production will simply shift to other countries.

According to nearly every drug and addiction expert I spoke with for *Fentanyl, Inc.*, decades of War on Drugs policies have failed to protect American users from overdose and death. Fortunately, America's political leaders are beginning to believe that care and treatment are more effective than incarceration, as shown by President Trump's signing of a pair of 2018 bills: one providing for better opioid treatment options, and another focused on criminal justice reform, which reduces some drug sentences. However, the criminal justice reform law specifically

excluded fentanyl offenders -- which was a mistake -- and many politicians continue to make the dubious distinction between users and dealers, considering that many addicted users become dealers simply to support their habits. "These aren't two distinct sets of people," Maryland public defender Kelly Casper told *Mother Jones*. "They want to charge all of these people with drug dealing, when in fact the core of the problem is that they're users.

Advocates of harm reduction believe that drug use is inevitable, and that we must work to make it as safe as possible. Curbing the tide of U.S. opioid deaths will require sweeping new harm reduction-focused public-health initiatives, including much-increased levels of funding for treatment programs like medication-assisted treatment. First responders, police, firefighters, and others who encounter overdose victims need to be better supplied with naloxone, which should be available and affordable to everyone.

Also critical is increasing users' access to drug-checking kits. These are inexpensive tests that inform users what's in their drugs, and can immediately detect the presence of drugs like fentanyl. These tests, made by companies like Bunk Police, serve as a form of prevention and save lives. A 2017 study carried out in Vancouver, British Columbia found that those who discover fentanyl in their drugs are ten times likelier to lower their dose, which makes them 25 percent less likely to overdose. "Drug users are far more rational than we make them out to be," said Dan Ciccarone, a University of California, San Francisco doctor who is an expert in this field, told *The Cut*. Also critical is overturning the Illicit Drug Anti-Proliferation Act of 2003, known informally as the RAVE Act, which effectively inhibits concert organizers from allowing drug-checking at their events and festivals. Many young people die of drug overdoses at these events every year, lives that could be saved if this legislation were overturned.

Information campaigns about fentanyl and NPS are also critical. Rather than simply preaching "Just Say No," users must have reliable, accurate information, to know the dangers of hyperpotent new synthetic drugs like fentanyl and K2/Spice (also known as synthetic cannabinoids), compared to traditional, plant-based drugs like heroin and marijuana. It's one thing to experiment, but when people know that the drugs in their hands could kill them instantly, they're more likely to use caution.

Information campaigns are vital at schools, hospitals, youth centers, treatment centers, and elsewhere. During my reporting I visited the suburbs of Dallas, Texas, which has been hit especially hard by these new drugs. A substance abuse counselor there named Grace Raulston told me that the K2 menace in the area was significantly reduced after an information campaign was disseminated. "The biggest thing we're fighting now is education. The majority of people out there—parents especially—do not have any idea the scope of the problem we're dealing with today," said Courtney Pero, a narcotics sergeant from Plano, Texas.

Parents need to believe that an overdose could happen to their kid, because it can happen to any kid.