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Drugs, Pills and Lawsuits : the Opioid Debacle

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I focus on the pain
The only thing that's real
The needle tears a hole
The old familiar sting
Try to kill it all away
But I remember everything
Hurt, song by Nine Inch Nails

We learn from history that we do not learn from history.
G. W. F. Hegel

Opioid medicines (medications) are a necessity. Without them, surgery or end-of-life (palliative) care could simply not proceed. Opioids are used every day to assuage intense acute pain. In Switzerland, accessing opioids for such legitimate medical purpose is largely a matter of course.

But opioids medicines also have a dark side – which has been known for decades. In the long-term, they are *not* very effective for chronic pain (e.g., back pain, arthrosis pain) ; prolonged use of such medicines leads to dose tolerance and could even increase the pain (by a mechanism of hypersensitization). Most importantly, opioids medicines cause first physical dependence, and then sometimes addictive disorders (an opioid dependence syndrome). This is true even in patients who took them for a medical purpose which was initially legitimate (e.g., to alleviate pain from a car accident). Finally, opioid medicines

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having a value on the black market (illicit drug market), they can be diverted to be sold for non-medical use or to dependent individuals.

The benefits of opioids have therefore to be balanced against their risks. In other words, benefits should be maximized, making sure that everyone who truly needs opioids receive them at the right time, at the right dose and in the right setting. Similarly, adverse consequences should be minimized, by detecting patients who should not receive opioids for their pain, by reducing the amount or duration of prescription for others, by securing the distribution channels, and by making sure that people who became dependent can access therapy, including opioid-agonist therapy (also called opioid maintenance therapy, typically with methadone or buprenorphine). However, it should not be forgotten that risks cannot be entirely averted, unless the benefits

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are also jeopardized. Moreover, opioid medicines have many (illicit) substitutes, that can be even more dangerous in many regards (smaller therapeutic window, adulteration, less medical control, higher addiction potential, methods of administration entailing contagion risks). Therefore, focusing efforts only on reducing the risks attached to opioid medicines may lead to greater risks associated with the use of street heroin, fentanyl derivatives, carfentanyl or any of the innumerable substitutes.

Throughout history, this difficult question around the proper balance has been answered with many different perspectives and in many different settings. The emphasis, for example, can be put on public health, on human rights, on public security, on social costs, or individual responsibility. Depending on the outlook retained, the resulting policies will be very different. For example, public health policies seek to improve the health of the entire population, using means such as information, prevention, medical treatment and nudges. A criminal perspective will tend to jail individuals trafficking or sometimes just using drugs (i.e., narcotics or more properly “substances under control”), removing them temporarily from society and thus reducing in the short-term the inconveniences and/or (supposed) dangers of their presence.

Here we choose to look at an unusual perspective, that of the lawsuit. In Switzerland, civil lawsuits are considered mainly as a tool for an injured party to obtain compensation for the financial or the moral harm he or she incurred. This is indeed the purpose of the vast majorities of lawsuits.

Yet, in the United States, opioid litigation has many additional purposes. They are a tool to shape policies, sometimes even in the long-term. Because finding agreement in the federal Congress or in State congress is often elusive, lawsuits, whether the ones that are settled, the ones decided before the court or the one which are still pending, can - somewhat more easily - impose new rules of conduct.

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The opioid litigation has aimed to correct the allegedly abusive practices of many actors involved in what has been termed the “opioid epidemic”. In this article, we start with a short summary of the various lawsuits, including their legal grounds. Then, we review the obstacles. Third, we ponder what will be the likely consequences in the United States. Finally, in our conclusion, we review the possible lessons for Switzerland.

1. Opioid litigation in the United States : an overview

Opioid use and dependence have always existed, at least as early as opium could be derived from poppy plants, or heroin purified from morphine. Interestingly, heroin, discovered in the late -19th century, was first thought to be a possible remedy against morphine dependence, while morphine, which had been isolated some 75 years previously, had been thought to be a possible remedy against opium addiction.

In the United States, the dangers of addiction were identified early and the first piece of legislation to address them was the Smoking Opium Exclusion Act of 1909 followed by a more severe version of 1914 (Harrison Narcotics Tax Act) and then 1924 (Anti-Heroin Act). It was not very effective, since medicines could still be sold without a proper label, no proof of safety nor efficacy. A true scientific system to evaluate new medicines was slowly put in place between 1960 and 1980. The pillars of this regulatory system have remained largely unchanged. For drugs which entail a potential to cause dependence, the U.S. FDA remains the entity in charge of deciding to grant approval, while the U.S. DEA decides to “schedule”, which carries additional control at the gross or retail distribution stage.

For a long time, opioid medicines were used sparingly, because mostly they had to injected. Patients being often wary of needles, they would not ask for them forcefully. Moreover, they could carry an image of end-of-life doom (“doctor, is it really *that bad* that I now need morphine ?”). This changed in the 1980s when oral forms came on the market and were aggressively marketed. Sales took off

In the United States, lawsuits by individual injured patients were filed soon after the launch of MS Contin (morphine sulfate) by the Sackler’s privately held firm Purdue in 1987. However, the problems really started with the 1995 approval of OxyContin (oxycodone) developed and sold by Purdue. The company was able to increase its sales volume very fast, reaching some 520 million pills in 2011 for a turnover nearing $3 billion. Every age group started to take OxyContin, and not just the elderly. OxyContin was prescribed for all kinds of pain, including dental pain.

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Soon after, in 2003, mass personal injury lawsuits were filed against Purdue - and settled. Years later, in 2007, the State of Kentucky first sued – successfully but recovering through the settlement “only” $24 million.

Yet, the dangers and the abuse in connection with OxyContin were known almost from the beginning and at least from 2000. In 2003, the Food and Drug Administration sent Purdue, the pharmaceutical company marketing OxyContin, a so-called Warning Letter, criticizing the firm for unduly minimizing the drug’s “serious

safety risks" and promoting it for unapproved off-label uses. The FDA required the firm to "provid[e] a plan of action to disseminate accurate and complete information to the audience(s) that received the misleading messages."

The settlement that the Purdue company reached with the U.S. Department of Justice and the Virginia Attorney General in 2007 is more typical of what is now happening. Following a 5-year investigation, Purdue admitted that it had marketed its new drug deceptively, falsely promising that OxyContin could provide 12-hour pain relief, without causing dependence. It entered into a (guilty) plea agreement as well as a five-year Corporate Integrity Agreement (CIA) with the U.S. Office of Inspector General. Under the former, it paid $654 million to the government. Three of its top executives (but none of Sackler family members) agreed to sentences of $24 million fines and services. This first settlement received a large media echo at the time. But its lessons were soon to be forgotten. Under the CIA, Purdue agreed to improve its internal procedures to ensure better compliance with U.S. laws ; it undertook to offer better training to its drug representatives (marketing staff).

Starting around 2005, the US DOJ launched many lawsuits against individual physicians and pharmacists. It accused them of dispensing excessive prescriptions without proper medical investigations. Criminal sanctions were imposed. The so-called "pill mill" phenomena took center stage among media reports, at times making us forget that reasonable physicians addressing genuine medical needs were also scared away from prescribing opioid medicines. This would soon carry heavy consequences.

It was not until 2010 that the U.S. realized it had grown a massive opioid use and overdose problem. According to the most recent numbers, only in 2019, there have been over 70'000 lethal opioid intoxications (overdoses), more than car accidents. Since the launch of Purdue's OxyContin in late 1985, an estimated half a million people (of all ages) have died due to the associated ills, mostly overdoses. This compares to less than 20'000 overdose deaths in 1999. Additionally, there have been nearly 1 million non-fatal drug intoxications. About 3 million individuals are suffering from opioid dependence. The U.S. life expectancy has decreased for three consecutive years (since 2016). Dependence

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syndromes that began with prescription opioids has first and primarily hit a white male population, making the problem more visible - and more socially acceptable than when, for example, crack cocaine was perceived to be consumed mostly by black Americans in the mid-1980s. Opioid dependence has been termed a disease of despair, because it affects a middle-class that has lost its status and economic prospects. In the United States, opioid dependence syndrome is more frequent in poor, rural, and central communities – at least much more so than previous peaks of drug consumption. Because these communities are already financially fragile, the social costs of drug addiction carry a huge burden. They have increased Medicaid and Medicaid expenses, the bills for mandatory-free urgent hospital care are soaring, rapid responders (police/fireman) are put under pressure, people are losing their jobs, kids are losing their parents to death, incarceration, and babies are born suffering from (albeit treatable) Neonatal Abstinence Syndrome.

Acknowledging these direct, indirect costs, States and local governments have started a flurry of lawsuits in various State courts throughout the United States. The lawsuits number in the three thousand with over 600'000 claimants. The first ones have begun to settle.

Indeed, in 2019, Purdue settled a lawsuit initiated by the State of Oklahoma for $270 million. A few months later, in 2019, the company chose to go into chapter 11 bankruptcy proceeding. Under this scheme, it is to become an independent public (non-profit) trust company. In the fall 2020, Purdue pled guilty to three felonies (conspiracy to defraud the United States, violation of the Food, Drug, and Cosmetic Act, violation of the Federal Anti-Kickback Statute). It agreed to pay $8 billion in fines. In addition, the Sackler family, owners of Purdue, has agreed to pay about $4.3 billion over a period of several years. In exchange, the family would be protected from all further lawsuits. In 2020, Johnson & Johnson proposed $5 billion to settle the lawsuits brought against its two (much less used) opioid Duragesic (fentanyl) and Nucynta (tapentadol). Teva proposed to pay $250 million, while also donating drugs for a $23 billion value. These offers have not yet been accepted.

The most-advanced of the various class actions - *In Re National Prescription Opioid Litigation* of the Northern District of Ohio (Cleveland) involving some 3'000 plaintiffs– is not even expected to go to trial. Settlement is the admitted aim ; a global solution would be ideal. It would further encompass the main US drug distributors – Walmart, McKesson., AmerisourceBergen and Cardinal Health – and large pharmacy chains – Walgreens, CVS, Rite-Aid.

As made clear form the above, the lawsuits and class actions have not just targeted companies manufacturing the opioid medicines. Interestingly, even McKinsey had to pay. The consulting firm had been retained by Purdue to help

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promote OxyContin. In 2021, it settled for nearly $600 million. As stated by the New York Times, this is “a rare instance of [such a firm] being held publicly accountable for its work with clients”.

Only the federal government, the FDA and the DEA, and insurers seem to have - so far – escaped the lawsuits bonanza. Yet, many believe that government entities also bear responsibility and might still be sued.

In comparison, outside of the United States, lawsuits have been rare and success rarer. A class action was introduced in Canada, but so far with no recovery in sight ; similarly, in Australia, litigation efforts are also underway.

2. Obstacles to the U.S. lawsuits

Despite the success of some of the lawsuits, they still face considerable obstacles, making them a double-edged sword to address social problems.

The first and main obstacle is very practical and has to do with the number of claimants. Judges have to rule on lawsuits launched by nearly all States, as well as thousands of local communities, injured adults, and even infants. As mentioned above, the defendants range from large multinational pharmaceutical companies (Johnson & Johnson, mainly for its role as manufacturer) to small distributors, and even individual physicians and pharmacists. In most instances, harms could only result from the combined actions of every actor of the chain. The physician wrote a prescription because both her medical associations and the insurance companies are insisting that pain should always be properly addressed. Moreover, she knows that long-term treatment of pain (e.g. psychotherapy or physiotherapy) will probably not be reimbursed, even though it is effective, perhaps even more effective than opioid pills. She also knows that her patient might well rate her badly if she issues no prescription. In the United States, surprisingly enough, prescription drugs can be advertised directly to patients, so that the latter often come to their doctors with requests for medications that they saw on TV. Once, the prescription is written, it will be dispensed by a pharmacy or pharmacy chain. The pharmacist is supposed to check whether the prescription is valid, including if the amounts and doses dispenses appear reasonable. However, the pharmacist has often no time to do so, because he is pressured to deliver bottles within a set amount of time. Moreover, the process to refuse to honor a prescription and negotiate with the prescriber and the patient is complex ; it involves much more hassle than simply delivering what the doctor ordered. Pharmacies have also been sued for refusing to dispense opioid prescriptions.

Of course, no opioid medicines could be dispensed if they were not delivered by distributors to pharmacies. Distributors are legally required to

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verify that they only deliver to reputable pharmacies, ensuring that opioids are not diverted for improper use. However, they have little financial incentives to do so, because the more they deliver, the more money they earn, especially if – as in the case of Walmart – they also own pharmacies. As a result, they often do not conduct the mandated controls, even in obvious situations.

Going up the chain, nothing would be possible without the pharmaceutical companies that manufacture the opioid medicines and that secure the necessary approval from the FDA. Opioid medicines have been on the market for many years, so that the basic ingredients are no longer patent-protected. However, because patent law is very flexible and encourage the patenting of even minor innovation, companies have succeeded in obtaining additional patent for incremental development, such as drug combination (oxycodone+ naloxone) or supposedly tamper-proof formulation (e.g., OxyContin OP approved in 2010). Undeniably, the medicines are safe and effective, if properly used (e.g., immediately after important surgery, cancer pain, end-of-life palliative care). Therefore, obtaining the necessary marketing approval from the FDA is no huge obstacle. Yet, wide-spread use outside the typical indication is usually not well studied, and the FDA has not acted to mandate these studies, even though it has the legal authority to do so. More precisely, to this date, no adequately powered and controlled randomized trial of opioid medicines for chronic pain has been submitted nor analyzed by the FDA. Yet, most opioid prescriptions were written for chronic pain in the United States.

Once the drug has received its marketing approval, pharmaceutical companies can and are adamant to market it as widely as possible. Their marketing campaigns are not subject to *ex ante* controls by the FDA, whereas the *ex post* controls have grown looser over time. Moreover, in the United States, free commercial speech protected by the First Amendment makes its significantly more complicated to control advertising. Indeed, States agencies bear the burden of proving breach of the law ; they must establish deception or misleading intent and demonstrate that the corrective measures required are the least intrusive possible. Over the years, this has grown to be an insuperable obstacle.

Additionally, pharmaceutical companies have realized that classic advertising, through newspaper ads, is not very effective. Increasingly, companies have relied on physicians used as tools to diffuse marketing messages among their peers. They have paid – and richly so – doctors to give talks in which the company's message is spread among doctors. Even though the practice of making gifts to doctors that are high prescribers has been curtailed by anti-kickback and false claims act litigation, it still exists in other forms.

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Pharmaceutical companies have also wooed medical societies and associations. Pain became the fifth vital sign (after temperature, pulse rate, respiration rate and pressure) in the early-1990s encouraged by the American Pain Society. However, most of the physicians decision-makers and key opinion leaders (KOLs) had ties with pharmaceutical companies selling opioid medicines. This is not to imply that pain should not be a vital sign. Afterall, 20% or more of the adult population suffers from chronic pain. But the initial message was twisted to mean that pain had necessarily and systematically to be "treated" by opioid medicines. The risk of the message being misunderstood should have - and could have - been recognized immediately.

Pharmaceutical companies realized early that their products were addictive and were used by a large number of patients who should not or no longer take them. Yet, they did next to nothing to diminish the amounts sold. The numbers were available to them and could have raised a red flag even in someone with no medical or epidemiological background. Pharmaceutical companies in the United States have at their disposal very precise numbers about the number of prescriptions delivered by (almost) each doctor and (almost) each pharmacy. They could have tracked the numbers and identified outliers, that is physicians / pharmacists that write / deliver significantly more opioid prescriptions that others (with the same specialty and in the same type of community).

As alluded above, governments also carry significant responsibility. To write a prescription for opioids, the physician must have a DEA authorization. The same is true for pharmacists. The DEA has access to precise numbers about the number of pills prescribed and delivered. It could have done the same analysis as pharmaceutical companies. Then, it could have withdrawn the DEA authorization, thus excluding from the market the proverbial "bad apples". Moreover, the federal and State governments have failed to make treatment for dependence syndromes easily available, even though providing proper treatment is - undeniably - a basic human rights protected under international conventions.

Thus, when someone has become dependent on prescription opioids, he or she will find it very difficult to receive proper treatment with opioid agonist therapy (methadone or buprenorphine). In Switzerland, by comparison, anyone seeking treatment for opioid addiction can avail himself or herself from a range of effective and reimbursed treatment, located near his or her domicile and with no delay. In the United States, the reverse is almost true. Additionally, considerable social stigma is attached to many forms of treatments (e.g., methadone administration being authorized for use only by a subset of specially trained physicians). A further and yet connected reproach levelled against the government is related to its clamping down on physicians' prescriptions. In 2010, the federal government started to impose much stricter rules on the

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quantities of opioid drugs that could be prescribed. It also sued and "raided" several physicians. The reaction was expected : most doctors severely curtailed their prescribing volume, provoking withdrawal syndromes in their dependent patients. This had one simple consequence : dependent patients turned to "street" alternatives, such as heroin, since medical treatment was, as just mentioned, almost inexistent. At the same time (2010), Purdue replaced its initial OxyContin drug by a pharmaceutical form that could no longer be sniffed or injected. This, combined with the contamination of street heroin with highly potent fentanyl or carfentanyl, led to an explosion of the numbers of lethal intoxications. Indeed, the risk of fatal overdoses is lower if the person sticks with ingesting the set number of prescribed pills, because both the dose and the concentration are known and the individual has no reason to change them markedly. He or she will either remain on the same dose or increase it in increments. The situation is very different when one is forced to acquire whatever is available, unlabeled, on the street. Moreover, street heroin is usually sold at a much lower price than prescription opioids (Oxycontin costs between $50 and $200 for 60 pills, but can garner a street price of 20 times that amount). Thus, when the individual can no longer rely on medically reimbursed prescription, but must finance his or her cravings out-of-pocket, cost becomes an important consideration.

From the above, we understand that apportioning the blame among the different parties at issue is extremely complex. The "opioid overdose epidemic" occurred because of a confluence of intertwined actions.

A similar problem occurs at the other end, the distribution of proceeds. Who should be indemnified ? Should it be the State government, the local government financing the hospitals and the first responders ? Should the funds be used to reimburse past expenses or to fund new measures ? These issues are controversial as settlements only succeeds if all or most complainants agree to it. In the present instances, the interests of all

plaintiffs are not aligned. Moreover, lessons learned from the Tobacco Settlement have made all parties aware of the significant risk for fund diversions. Usually, the most powerful parties, State legislatures, tend to divert settlements funds for what they see as higher constituent priorities (e.g., law enforcement, school construction, or general budgets). Hence, less than 3% of the Tobacco Settlement funds are being used for tobacco prevention and treatment of associated problems. To avoid repeating the same mistake, the opioid settlement must include from the start binding (and unalterable) clauses about the specific use of funds. But this makes finding consensus even more difficult, since the agreement must not only cover who will receive how much, but also for which purpose.

The need for transparency has also proven to be tricky. Ideally, plaintiffs want full access to the internal documents of the defendants, so that the latter

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can be made public. Only then, can all involved stakeholders learn from the mistakes made or the deception suffered. The defendants resist this call for transparency, because that could increase their liability elsewhere, notably in other countries. Even though the 1998 US Tobacco Settlement was not “imitated” elsewhere, more than 20 years have lapsed. In the meanwhile, a few other countries beyond the US have developed a taste for class actions. Canada has launched its own series of lawsuits. If other countries could use documents unearthed in the US litigation, their tasks and litigation strategy would be made much simpler.

3. The consequences of the opioid litigation in the United States

The opioid lawsuits have brought with them intense media attention. There are newspaper articles and TV reports about the opioid epidemic practically every day in practically every outlet. Litigation also brings along a certain suspense that sustains media attention. Even, Dan A. Polster, the judge overseeing the above-mentioned Cleveland opioid multi-district litigation (MDL), has been a target of unusual media attention.

Along with this media focus comes scholarly notice. The numbers of legal articles written on the subject has soared in the United States. Indeed, the lawsuits raise many interesting legal questions, such as the application of the common-law public nuisance claim to obtain remediation costs or the procedural “Negotiation Class” to facilitate class action resolution. That these questions have not been answered by the Courts and likely will not ever, leaves plenty of room and leeway for scholarly contributions and analyses.

States agencies have joined in, with their own analyses. The National Institutes of Health have launched various initiatives and research programs. Official medical guidelines have been issued. Hundreds if not thousands of law review articles have studied the various legal aspects of the ongoing litigation efforts.

From these numerous reports, many different solutions have emerged. Advice has been given on how to structure mass litigation, how to apportion funds in binding manners, how to fight opioid addiction. Bills were voted. Improved therapy for patients was made available - albeit slowly. Instead of just emphasizing the “War on Drugs”, a multi-pronged approach was privileged.

4. Implications for Switzerland ?

Even though use of opioid medications has markedly increased, Switzerland is currently not facing an opioid “epidemic”. At least nothing comparable to the number of deaths occurring in the United States. However, when searching for

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precise numbers (e.g., how many tramadol pills were prescribed in Geneva to patients over 65 of age over the last 10 years), we find that Switzerland is unable to monitor closely any potential problem. If a problem were to develop, our health agencies at the federal and at the cantonal level would probably only realize it, once made highly visible by hospitalizations or deaths.

Indeed, cantonal health authorities are neither collecting nor analyzing the numbers of prescriptions for controlled substances, such as opioids, benzodiazepines or Z-drugs. The Federal Office for Public Health is not doing it either. We do have survey information available, but these data are too rough to distinguish between proper or risky use. Moreover, they suffer from a significant time lag.

Ironically, Switzerland has excellent data about people under medically assisted opioid agonist treatment for syndromes of dependence. For this population, we know exactly who is receiving what, when and where. It seems that that people under medically supervised treatment require tighter State controls than those who might be abusing drugs and medicines.

If one is to learn anything from the US debacle, it is that, for problems to be addressed, the first steps are to gather *and use* the data. If either or both the pharmaceutical companies and the public agencies had used, analyzed and released their data, the problems would have been identified sooner and the proper remedies would have been applied in due time (e.g., exercising tight oversight over advertising, closing pill mills, offering proper medical treatment to people who have become dependent).

There are probably no perfect solutions because, as discussed in chapter 1, a balance must necessarily be reached between legitimate access to necessary opioids and proper surveillance measures against diversions and dangerous use. Moreover, often when many parties share responsibilities, none of them assumes the lead in implementing solutions.

In the United States, litigation has helped to garner intense attention of journalists, politicians, scholars, civil servants. The same tend to happen in Switzerland, when litigation takes place – think about the fiscal fraud lawsuits or money laundering lawsuits. When the Yasmin/Céline lawsuit took place, it also sparked an intense debate about the merits and risks of contraceptive pills.

No opioid lawsuit has been launched in Switzerland, despite the fact that some patients have become addicted to prescribed opioid medicines. Yet, that such lawsuit would take place in the near future is unlikely – that a plaintiff in such a lawsuit could prevail even more so. In Switzerland, marketing of medicines is more severely regulated. Direct-to-consumer advertising of (any) prescription drugs is banned. Marketing techniques are usually more muted.

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Speaker and advisory boards do exist, but the financial payments they offer to physicians are subject to severe constraints. The legal theories to recoup damages for the harm of opioids are also more limited in Switzerland. Only injured patients would have some (low) odds of compensation, by showing that the medicines they took were defective (e.g., defective label) under the Federal Product Liability Act or that the pharmaceutical company knew or should have known of a risk but did not act diligently to address the risk under civil liability of Article 41 or 55 of the Code of obligations. State actors, whether federal or cantonal, could not sue in Switzerland for civil damages, because they only incurred indirect economic damages and because no provisions meant to protect their economic interest was infringed (no illicit action under the theory of "*illicéité de comportement*").

Of course, State actors could exercise administrative powers over pharmaceutical companies, pharmacists and physicians. However, the aim of such actions is much more limited, since it targets a specific behavior or series of behavior. Moreover, the cost for the State in bringing forward such administrative lawsuits is almost equivalent to the financial benefits collected as fines.

Criminal lawsuits have even less efficacy in Switzerland. Except for Article 102 Criminal Code, they can only target the individuals, not the pharmaceutical companies. Their odds of success are low.

5. Conclusion

Each country follows its own path, sometimes moved by the example of others, sometimes put off by their mishaps. Interestingly, because our world has become so global, even when we reject foreign models, we are still influenced by them. While, in the recent past, companies could adhere to higher norms of conduct in certain countries, while disdaining them in less fortunate ones, this ambiguous, or even contradictory, attitude has become risky.

Even in Switzerland, we learn from the U.S. catastrophe. We are reminded of the dangers. Pain control has become a theme of common interest. The opioid lawsuits are likely to have a deterrent effect beyond North America. In a way, we are piggybacking on their endeavors. Yet, this should not adjourn our own reflections on the necessary system reforms. That our laws and procedures make it very difficult to successfully challenge misleading pharmaceutical practices should give us pause. Fortunately, evidence-based medical treatments remain widely available.

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To learn more…

Aliferov, Edgar., The Role of Direct-Injury Government-Entity Lawsuits in the Opiod Litigation, Fordham Law Review, Vol. 87, 2018.

Ausness, Richard C., A Progress Report on Opioid Litigation, Journal of Legal Medicine, 40:3-4, 429-446, 2020.

Baker David W., The Joint Commission's Pain Standards : Origins and Evolution, The Joint Commission, 2017.

Booth, Martin, Opium : A History, 1999.

Broers, Barbara Opioïdes : épidémie ou mal nécessaire ? présentation powerpoint à la Primary Care Academy du 6 mars 2020.

CSR (Congressional Research Service), The Opioid Epidemic : Supply Control and Criminal Justice Policy—Frequently Asked Questions, 2018.

Dasgupta Nabarun et al., 'Opioid crisis : No easy fix to its social and economic determinants', American Journal of Public Health, 2018.

Engstrom Nora F. / Rabin Robert L., Pursuing Public Health Through Ltigation, Stanford Law Review 73 2021.

FDA, Warning letter to Purdue, 2003.

FDA, Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse, https://www.fda.gov/media/126835/ download (last consulted 21.05.2021).

Freeman, Nora *et al*., Pursuing Public Health Through Litigation, Stanford Law Review.

Gaertner, Katharina *et al*., Prevalence and practice of opioid prescription at a Swiss emergency department : 2013–2017, Swiss Med Wkly. 2020; 150:w20202.

GAO (Government Accountability Office), OxyContin Abuse and Diversion and Efforts to Address the Problem, 2003.

GAO, Opioid Crisis : Status of Public Health Emergency Authorities, 2018.

GAO, Actions Needed to Ensure Usefulness of Data on Suspicious Opioid Orders, 2020.

GAO, Synthetic Opioids, Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances, 2021.

Global Commission on Drugs, Position paper, The opioid crisis in North America, October 2017.

Gmel, Gerhard *et al*., Suchtmonitoring Schweiz – Einnahme von psychoaktiven Medikamenten in der Schweiz im Jahr 2016 [Addiction Monitoring

180

Switzerland – intake of psychoactive drugs in Switzerland in 2016], Lausanne, Sucht Schweiz 2018.

Hoffman, Jan, Can This Judge Solve the Opioid Crisis ? New York Times of March 5, 2018.

Hollis, Addison, A Wanted Opioid-Addiction Challenge : How Should Louisiana Allocate Proceeds from Opioid Litigation ? Louisiana Law Review, Vol. 81 Number 1 Fall 2020 Article 13.

Kassirer, Jerome P., Professional societies and industry support : What is the quid pro quo ? Perspect Biol Med 50:7-17, 2007.

LeBaron, Virginia *et al.*, Opioid Epidemic or Pain Crisis ? Using the Virginia All Payer Claims Database to Describe Opioid Medication Prescribing Patterns and Potential Harms for Patients With Cancer', *Journal of Oncology Practice*, 15(12), pp. e997–e1009, 2019.

Marks, Jonathan H., Lessons from Corporate Influence in the Opioid Epidemic : Toward a Norm of Separation, Journal of Bioethical Inquiry 17:173–189, 2020.

McCollum Morgan A., Local government plaintiffs and the opioid multi-district litigation, 94 New York University Law Review 938, 2019.

Meier, Barry, Pain Killer : A Wonder Drug's Trail of Addiction and Death, 2003.

Morone, Natalia E. / Weiner, Debra K., Pain as the Fifth Vital Sign : Exposing the Vital Need for Pain Education, Clinical Therapeutics, 35:11, 2013.

NIH, NIH HEAL Initiative Research Plan, https://heal.nih.gov/ about/research-plan (last consulted 31.05.2021).

Noll David L., MDL as Public Administration, 118 Michigan Law Review 403, 2019.

Orrick, Elizabeth, Mistakes were Made : Applying Lessons Learned from the Tobacco Master Settlement Agreement to the Opioid Settlement Agreement, Mitchell Hamline Law Journal of Public Policy and Practice Vol. 42, Issue 1 Article 1, 2021.

Purcell, Michael J., Settling High : A Common Law Public Nuisance Response to the Opioid Epidemic, Journal of Law & Social Problems, Vol. 52, 2018-2019.

Quinones, Sam, Dreamland : the true tale of America's Opiate Epidemic, 2015.

Radden Keefe, Patrick, Empire of pain, The Secret History of the Sackler Dynasty, Doubleday, 2021.

Ruchat, David *et al*., Consommation d'opioïdes entre 1985 et 2015 : chiffres suisses et mise en perspective internationale, Revue Médicale Suisse 2018, 14(612):1262–1266.

181

Scholten Willem *et al*., Access to treatment with controlled medicines rationale and recommendations for neutral, precise, and respectful language, Review paper, Public Health 153 (2017):147-153.

Scholten Willem, European Drug Report 2017 and opioid-induced deaths. (Editorial) Eur J Hosp Pharm 2017; 24(5):256-7.

Scholten Willem / Henningfield JE, Negative outcomes of unbalanced opioid policy supported by clinicians, politicians, and the media. J Pain Palliative Care Pharmacother. (2016) 30:1, 4-12.

Terry, Nicolas P., The Opioid Litigation Unicorn, South Carolina Law Review, Vol. 70, 637.

Van Zee, Art, The Promotion and Marketing of OxyContin : Commercial Triumph, Public Health Tragedy, Am J Public Health, 2009 February, 99(2):21–227.

Walley, A. Y. *et al.* (2019) 'The Contribution of Prescribed and Illicit Opioids to Fatal Overdoses in Massachusetts, 2013-2015', *Public Health Reports*. SAGE Publications Inc, 134(6), pp. 667–674.

Wertli, Maria M *et al*., Changes over time in prescription practices of pain medications in Switzerland between 2006 and 2013 : an analysis of insurance claims. BMC Health Serv Res. 2017;17(1):167. doi : http://dx.doi.org/10.1186/s12913-017-2086-6 (last consulted 31.05.2021).

Wiersum, Carl, No Longer Business as Usual : FDA Exceptionalism, Commercial Speech, and the First Amendment, Food and Drug Law Journal, 73:4, 2018.