“You are not a horse.” – How the US Court’s Ruling on COVID and Ivermectin Impacts Global Industries

September 5, 2023

In an era marked by the global upheaval of the COVID-19 pandemic and the ensuing debates around treatments like Ivermectin, a recent pivotal U.S. Court of Appeals for the Fifth Circuit judgment serves as a beacon of clarity, in Apter et al. v. Dep’t of Health & Human Services et al (No. 22-40802).

The judgment, which delves into the nuanced distinction “between telling about and telling to,” has implications that reverberate far beyond the healthcare sector. It serves as a timely reminder of the delicate balance that regulatory bodies must maintain in their interactions with various industries.

The judgment comes at a critical juncture, where the line between guidance and directive action has been blurred by the urgency of the pandemic and the hyperbole that often accompanies it. In such times, the role of regulatory bodies becomes even more pivotal, not just in healthcare but across a spectrum of industries that form the backbone of modern society. From construction and finance to new technologies and private wealth management, the judgment underscores the importance of regulatory restraint and nuanced communication.

As we navigate through the complexities of this judgment, we will explore its implications across diverse sectors, shedding light on the intricate dance between regulatory bodies and

industries. This exploration is not just an academic exercise; it is a crucial endeavor to understand the commercial consequences and potential liabilities that may arise when industries rely on non-directive government policies, public instructions, private notifications, and more.

In the following sections, we will delve into the multifaceted interactions between regulatory bodies and various industries, offering a global perspective on a judgment that, while rooted in American jurisprudence, has global reverberations.

Background

The dispute involving the United States Food and Drug Administration ("FDA") and three medical practitioners ("the Doctors"). The crux of the issue lies in the FDA's public advisories concerning the use of the drug ivermectin for the treatment of COVID-19, and the alleged impact of these advisories on the medical practice of the Doctors.

The FDA, in its role as a regulatory body, issued public statements and utilized social media platforms to dissuade the general populace from employing ivermectin as a treatment for COVID-19. The agency employed phrases such as "You are not a horse" to underscore the point that ivermectin, particularly the version formulated for animals, is not approved for treating COVID-19 in humans. This messaging was part of a broader strategy aimed at public health and safety.

The Doctors, on the other hand, contend that they have been prescribing the human version of ivermectin to their patients as a treatment for COVID-19. They argue that the FDA's public advisories have not only interfered with their medical practice but have also inflicted reputational harm. They further assert that the FDA's actions are in violation of its enabling act and the Administrative Procedure Act.

The district court initially dismissed the Doctors' claims, invoking the doctrine of sovereign immunity to shield the FDA

and associated officials. However, the United States Court of Appeals for the Fifth Circuit took a divergent view. The Court held that the Doctors could indeed proceed with their claims under the Administrative Procedure Act, bypassing the barrier of sovereign immunity. The Court reasoned that the FDA's advisories could plausibly be considered "ultra vires" actions, as they ventured into the realm of medical advice, a domain not within the FDA's statutory mandate.

In light of the foregoing, the Court of Appeals reversed the district court's judgment and remanded the case for further proceedings. The Court of Appeals' judgment opens the door for a more nuanced exploration of the tension between regulatory advisories and the autonomy of private sector professionals.

Reasoning

The FDA had argued that the social media posts neither "directed" consumers nor any other parties to act or refrain from acting in a specific manner, and thus should not be classified as rules under administrative law.

Contrary to the FDA's position, the court found that the posts contained imperative elements that transcended the realm of mere factual dissemination. The FDA had also posited that these posts could not be considered rules as they did not "prescribe…policy." This line of argument was dismissed by the court, which noted that the FDA itself conceded that the posts "generally recommended that consumers not take ivermectin to prevent or treat COVID-19."

The court discerned no material distinction between an agency employing imperative language to recommend a general course of action and one employing similar language to prescribe a policy.

Moreover, the FDA's assertion that the posts were nonbinding and did not signify the conclusion of the agency's decisional process was found to conflate the criteria for determining

what constitutes action with those for determining finality. The court clarified that “nonfinal action” remains action under the law. It also rejected the FDA’s attempt to impose a finality requirement for a waiver of sovereign immunity, particularly in the context of the Doctors’ ultra vires claim, which constituted a non-statutory cause of action.

The court adjudicated that the posts constituted “agency action,” thereby laying down a legal benchmark that could profoundly affect the nuanced distinction “between telling about and telling to.” This verdict not only invites further judicial exploration but also carries sweeping implications across diverse sectors. Specifically, it raises questions about the commercial repercussions of depending on non-directive government policies and the potential liabilities that may arise as a result.

Finding

The court emphasized that while the FDA has the authority to “inform, announce, and apprise,” it does not possess the authority to “endorse, denounce, or advise” on medical matters.

The Doctors had plausibly alleged that the FDA’s posts crossed this critical boundary, shifting from the realm of “telling about” to “telling to.” The court agreed, affirming that the Doctors could use the Administrative Procedure Act to assert their ultra vires claims against the FDA and associated Officials.

The court went further to state that even “tweet-sized doses of personalized medical advice” are beyond the FDA’s statutory purview. This statement underscores the court’s view that the FDA had overstepped its regulatory mandate by issuing advisories that could be construed as medical advice or recommendations.

In overturning the district court’s dismissal and remanding

the case for further evaluation, the court's pivotal ruling not only sets the stage for more comprehensive judicial oversight but also establishes a crucial legal framework. This framework is particularly significant in delineating the fine line "between telling about and telling to." The verdict has wide-ranging implications across a variety of sectors, notably in the commercial sphere where businesses often rely on non-directive government policies as a basis for decision-making. The potential for liabilities stemming from such reliance becomes a critical concern, especially in an era where new media platforms like podcasts can amplify or challenge governmental advisories.

The Joe Rogan controversy over the use of ivermectin exemplifies the complexities of this landscape. Rogan's endorsement of the drug on his widely-followed podcast added another layer of public discourse, complicating the role of traditional regulatory advisories. In a world where new media can rival or even overshadow governmental instructions, the court's judgment serves as a timely reminder of the legal intricacies involved. It raises questions about how much weight should be given to government instructions in commercial activities and private sector disputes that may arise when those instructions are deemed to have crossed the line from informational to directive.

Thus, the ruling is not just a legal touchstone but also a lens through which to view the evolving dynamics between governmental advisories, new media influences like podcasts, and the commercial risks and disputes that may ensue from the interplay of these factors.

A Tapestry of Interactions Across Industries

This recent judgment by the U.S. Court of Appeals Fifth Circuit has cast a spotlight on the nuanced but pivotal distinction "between telling about and telling to." This distinction, while seemingly subtle, has far-reaching

implications across various sectors, particularly when it comes to the commercial consequences of relying on non-directive government policies and the liabilities that may ensue.

Following we aim to examine its far-reaching effects across various industries, illuminating the delicate interplay between regulatory authorities and commercial sectors. This investigation goes beyond mere scholarly inquiry; it serves as an essential effort to grasp the commercial ramifications and possible legal risks that could emerge when industries depend on non-directive governmental guidelines, public advisories, private alerts, and the like.

Construction / Infrastructure

In the construction and infrastructure sector, the distinction between regulatory guidance and directive action can have profound implications. For example, when a regulatory body merely informs about the safety standards for construction materials, contractors may interpret this as a green light to use specific materials in their projects. However, if those materials later prove to be substandard or unsafe, the contractors could face significant legal liabilities. Similarly, if a regulatory body provides information about environmental sustainability but stops short of issuing directives, construction firms may adopt certain green technologies. If these technologies later prove to be ineffective or problematic, the firms could face both reputational damage and legal challenges.

In the realm of construction and infrastructure, regulatory bodies are akin to architects sketching the outlines of a cityscape. Beyond mere guidelines, they often employ public consultations and even mobile apps to update contractors on safety norms. In Germany, the Federal Ministry of Transport and Digital Infrastructure uses social media to announce public hearings on new construction projects, inviting citizen

participation in shaping their own neighborhoods. In Australia, the Building Codes Board not only issues construction guidelines but also holds public forums where contractors and citizens alike can voice their concerns. In India, the Real Estate Regulatory Authority (RERA) sends SMS notifications to registered builders about compliance deadlines, making sure everyone is on the same page.

Insurance / Reinsurance

In the insurance and reinsurance sectors, the line between guidance and directive action is equally critical. Regulatory bodies often issue frameworks for risk assessment. If insurers interpret these frameworks as tacit approval for specific risk assessment models and those models later prove to be flawed, the insurers could face a slew of legal disputes from policyholders. Additionally, if regulatory bodies inform about but do not direct specific claims processes, insurers may adopt these processes as best practices. Should these processes later be found to violate consumer rights, the legal ramifications could be severe.

In the U.S., the National Association of Insurance Commissioners (NAIC) not only sets standards but also conducts webinars and podcasts to clarify complex insurance terms. Meanwhile, the UK's Prudential Regulation Authority sends out private notifications to insurers about risk assessment changes, ensuring a dynamic and responsive insurance landscape.

Biotech / Pharmaceuticals

In the biotech and pharmaceutical sectors, the stakes are incredibly high. Regulatory bodies frequently issue guidelines on drug safety and clinical trials. Companies may interpret these guidelines as endorsements of specific research methods or treatments. If these methods or treatments later prove to be harmful or ineffective, the companies could face not only

legal action but also severe reputational damage. Moreover, if regulatory bodies provide information about the efficacy of certain drugs but do not issue formal approvals, pharmaceutical companies may proceed with production. Should these drugs later be found to have adverse side effects, the companies could face both legal challenges and public backlash.

The European Medicines Agency (EMA) in the EU issue guidelines and also holds annual public meetings to discuss the ethical implications of new drugs. In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) uses newsletters to update companies on changes in clinical trial protocols, ensuring a seamless blend of innovation and safety.

Energy / Natural Resources

In the energy sector, the implications of the distinction between “telling about and telling to” are vast. Regulatory bodies often issue guidelines on sustainable energy practices. Energy companies may interpret these guidelines as an endorsement of specific technologies or methods. If these technologies later prove to be environmentally harmful or less efficient than initially thought, the companies could face legal action. Additionally, if regulatory bodies provide information about extraction methods without issuing directives, companies may proceed with extraction activities that later prove to be environmentally damaging, leading to both legal liabilities and reputational loss.

The U.S. Department of Energy not only sets efficiency standards but also releases interactive online tools that allow companies to calculate their carbon footprint. In Saudi Arabia, the Ministry of Energy utilizes SMS alerts to inform companies of shifts in oil production quotas, allowing for real-time adjustments.

Banking / Finance

In the banking and finance sectors, the line between regulatory guidance and directive action can have far-reaching implications. Regulatory bodies often issue guidelines on ethical investment and risk management. Financial institutions may interpret these guidelines as tacit approval for specific investment strategies. If these strategies later prove to be high-risk or unethical, the institutions could face both regulatory action and legal disputes from clients. Moreover, if regulatory bodies provide information about lending criteria without issuing formal directives, banks may adopt these criteria. Should these criteria later be found to be discriminatory or unfair, the banks could face legal challenges and reputational damage.

In the world of banking and finance, regulatory bodies act as the traffic lights at busy intersections. The Reserve Bank of India, for instance, employs a mobile app to update banks on changes in interest rates. In Switzerland, the Financial Market Supervisory Authority uses videos to explain complex financial instruments, making the arcane world of finance more accessible to the public.

Hospitality / Leisure

In the hospitality and leisure industry, the distinction between “telling about and telling to” can have significant operational implications. Regulatory bodies often issue guidelines on hygiene and safety standards. Hotel chains may interpret these guidelines as endorsements of specific cleaning products or methods. If these products or methods later prove to be ineffective or harmful, the chains could face legal action from guests. Similarly, if regulatory bodies provide information about licensing requirements without issuing directives, leisure facilities may proceed with operations that later prove to be non-compliant, leading to both legal action and reputational damage.

In the hospitality sector, regulatory bodies are the critics

who shape our leisure experiences. The U.S. Food and Drug Administration (FDA) not only sets hygiene standards for restaurants but also uses social media to alert the public about food recalls. In France, the Ministry of Culture employs virtual reality to offer virtual tours of new leisure spaces before they open, gathering public opinion in an interactive manner.

Retail / Consumer Goods

In the retail and consumer goods sector, the line between regulatory guidance and directive action is particularly salient. Regulatory bodies often issue safety standards for products. Manufacturers may interpret these standards as endorsements of specific materials or designs. If these materials or designs later prove to be unsafe, the manufacturers could face legal action from consumers. Moreover, if regulatory bodies provide information about labeling requirements without issuing directives, retailers may proceed with labeling that later proves to be misleading, leading to both legal challenges and a loss of consumer trust.

The UK’s Competition and Markets Authority uses Instagram stories to educate consumers about their rights. In Japan, the Consumer Affairs Agency employs QR codes on product labels to direct consumers to web pages detailing product recalls, ensuring that safety information is just a scan away.

Public Sector / Government

In the public sector, the implications of the distinction between “telling about and telling to” are vast. Regulatory bodies often issue guidelines on public service delivery. Government agencies may interpret these guidelines as endorsements of specific service delivery methods. If these methods later prove to be inefficient or ineffective, the agencies could face legal action from the public. Additionally, if regulatory bodies provide information about

budgetary allocations without issuing directives, government departments may proceed with spending that later proves to be wasteful, leading to both legal scrutiny and public outcry.

In the public sector, regulatory bodies are the architects of governance. The U.S. Federal Communications Commission (FCC) not only regulates media but also employs town halls to discuss public concerns about media ethics. In Sweden, the Ministry of Health and Social Affairs uses podcasts to update the public on changes in social welfare policies, making governance a two-way street.

Transportation / Logistics

In the transportation and logistics sectors, the line between regulatory guidance and directive action can have far-reaching implications. Regulatory bodies often issue safety and environmental guidelines. Logistics companies may interpret these guidelines as endorsements of specific shipping routes or cargo handling methods. If these routes or methods later prove to be unsafe or environmentally damaging, the companies could face legal action. Moreover, if regulatory bodies provide information about import/export regulations without issuing directives, companies may proceed with activities that later prove to be non-compliant, leading to both legal action and reputational damage.

In transportation and logistics, regulatory bodies are the navigators charting the course. The International Maritime Organization (IMO) not only sets shipping standards but also employs webinars to discuss the impact of new regulations on global trade routes. In China, the Ministry of Transport uses WeChat to update trucking companies on changes in road tariffs, ensuring smooth flow of goods.

Blockchain / Digital Assets

In the realm of blockchain and digital assets, the distinction between “telling about and telling to” can have significant

legal and financial implications. Regulatory bodies often issue guidelines on security and transparency. Companies operating in this space may interpret these guidelines as endorsements of specific blockchain protocols or trading platforms. If these protocols or platforms later prove to be insecure or non-transparent, the companies could face both legal action and a loss of investor trust.

In the realm of blockchain and digital assets, regulatory bodies are the pioneers mapping uncharted territories. The U.S. Commodity Futures Trading Commission (CFTC) not only sets trading standards but also uses Reddit AMAs to answer questions about digital assets. In Estonia, the Financial Intelligence Unit employs newsletters to update companies on anti-money laundering measures specific to digital currencies.

New Technologies / Space

In the realm of new technologies and space exploration, the line between regulatory guidance and directive action can have profound implications. Regulatory bodies often issue guidelines on safety and ethical considerations for new technologies. Companies may interpret these guidelines as endorsements of specific technologies or methods for space exploration. If these technologies or methods later prove to be unsafe or ethically problematic, the companies could face not only legal action but also severe reputational damage. Moreover, if regulatory bodies provide information about international collaborations in space exploration without issuing formal directives, companies may proceed with partnerships that later prove to be problematic, either due to technological failures or diplomatic tensions, leading to both legal challenges and a loss of public and international trust.

In the arena of new technologies and space exploration, regulatory bodies are the visionaries dreaming of new worlds. For instance, the European Space Agency (ESA) not only establishes protocols for satellite launches but also engages

with the public through interactive webinars to discuss the environmental impact of space debris. In Russia, the Federal Space Agency (Roscosmos) uses televised roundtables to discuss the ethical implications of space colonization.

Private Wealth / Families

For private wealth and family offices, the distinction between "telling about and telling to" can have significant financial and legal implications. Regulatory bodies often issue tax guidelines and estate planning recommendations. Wealth managers and family offices may interpret these guidelines as endorsements of specific investment vehicles or estate planning strategies. If these vehicles or strategies later prove to be less advantageous or even financially detrimental, the offices could face both legal scrutiny and financial loss. Similarly, if regulatory bodies provide information about charitable giving without issuing formal directives, families may proceed with donations that later prove to be non-compliant with tax laws, leading to both legal complications and potential financial penalties.

The U.S. Internal Revenue Service (IRS) not only sets tax guidelines but also employs webinars to discuss the implications of tax reforms on estate planning. In the UK, the Office of Tax Simplification uses newsletters to update family offices on changes in inheritance tax laws, ensuring that legacies are passed down in compliance with the law.

Conclusion

The Court of Appeals' recent judgment provides a practical framework for understanding the limits of regulatory authority. By focusing on the distinction "between telling about and telling to," the Court has clarified an important aspect of regulatory communication that is relevant across various sectors. In a digital age where information is easily accessible, the judgment underscores the need for both

regulators and industries to be cautious in how they issue and interpret guidance.

For regulatory bodies, the ruling serves as a reminder to be precise in their communications. Whether issuing public guidelines, private notifications, or other forms of instruction, regulators must be clear about the intent and scope of their messages to avoid crossing into directive action. This is particularly important in a fast-paced information environment where messages can be quickly disseminated and misinterpreted.

Industries also have a role to play in this dynamic. The Court's judgment highlights the importance of scrutinizing regulatory communications carefully. Companies need to consider the nature of these communications—whether they are guidelines, instructions, or other forms of information—when making business decisions. Misinterpreting the intent behind regulatory messages can lead to commercial risks and potential legal liabilities.

The judgment is also relevant for corporate strategists and policymakers. Corporate strategists can incorporate the ruling into their risk assessment processes, particularly when navigating regulatory environments, and policymakers can take the Court's insights into account when drafting new regulations, aiming for clarity and precision to minimize misunderstandings.

Overall, the Court of Appeals' judgment offers a balanced perspective on the boundaries of regulatory authority. It encourages both regulators and the regulated to exercise caution and due diligence in their interactions, highlighting the complexities and potential pitfalls in this area.

Author: Mahmoud Abuwasel
Title: Partner – Disputes
Email: mabuwasel@waselandwasel.com
Profile: https://waselandwasel.com/about/mahmoud-abuwasel/

Lawyers and consultants.
Tier-1 services since 1799.
www.waselandwasel.com
business@waselandwasel.com