Remarks by David Morrell to the Food and Drug Law Institute Annual Enforcement, Litigation, and Compliance Conference

I. Introduction

Thank you, Amy, for that kind introduction. Good morning everyone.

It is an honor to be here today at the Enforcement, Litigation, and Compliance Conference with so many distinguished participants from the legal and scientific communities.

I am here this morning to speak about the Department of Justice's enforcement work in the food, drug, and device space. That space is central to the work of my office—the Department's Consumer Protection Branch. The Branch, or CPB, as many of you know, is responsible for enforcing statutes that protect Americans' health, safety, economic security, and identity integrity. Though part of the Department's Civil Division, don't let the "Civil" moniker fool you—the Consumer Protection Branch advances its work using both criminal and civil tools, including criminal enforcement actions. It also defends consumer protection agencies—including the FDA—in federal litigation. In all of our work, we collaborate closely with our agency partners, law-enforcement investigators, and colleagues in the U.S. Attorneys' Offices.

Of most relevance to *this* Conference is the Consumer Protection Branch's work investigating and litigating civil and criminal violations of the Food, Drug, and Cosmetic Act and the Controlled Substances Act. Working closely with our friends at FDA and the Drug Enforcement Administration (DEA), we pursue actions under those laws with a focus on safety and compliance. We particularly understand that the FDCA and CSA are, at heart, public-health statutes and not just laws to punish wrongdoing. The public's safety depends on voluntary compliance up and down the product supply chain. And we know that the vast majority of individuals

and entities operating in the food and medical-product sectors share a commitment to voluntary compliance in developing and marketing life-saving and life-improving products.

But, of course, there are those who cut corners or engage in outright fraud. And since this is the Enforcement and Compliance Conference, I will focus this morning on some highlights of the Consumer Protection Branch's enforcement work from the last year and discuss how that work portends future action. I will then review some broader enforcement policies and trends that will guide the Branch moving forward.

II. CPB Enforcement Highlights

The first thing to note in highlighting the Consumer Protection Branch's work this past year is that we have been very busy and quickly growing. Charged with leading Department responses to a host of public health and safety crises, CPB has been bolstered by the Trump Administration. Indeed, the Branch has grown from fewer than 40 attorneys in 2017 to nearly 70 today, and we have more than tripled our support staff of law clerks, paralegals, and investigators. We also, as I will discuss later, have developed new analytical tools and built partnerships that expand our capabilities.

With these increased resources, the Branch has focused its FDCA and CSA efforts this year on five key areas: dietary supplement fraud, the prescription opioid crisis, regulatory deception, sterile compounding violations, and vaping. Our work in each area is directed at addressing and preventing consumer harm. Sometimes this follows from an incident of consumer harm. Other times, our work flows from repeated regulatory violations that are *likely* to cause harm. FDA and the DEA have their own enforcement tools. But we get involved if those tools fail to bring a bad

actor into compliance—exercising our independent litigating authority and judgment to seek relief.

A. Dietary Supplements

Turning to dietary supplements: everyone in this room knows that Americans are taking more dietary supplements, such as vitamins and minerals. Three out of every four American consumers take a dietary supplement on a regular basis. In older Americans, the rate rises to four out of five. What was once a $4 billion industry comprising about 4,000 unique products, is now an industry worth more than $130 billion, with more than 50,000 different products available to consumers. In just a few years, the supplement industry will be worth hundreds of billions of dollars.

Former FDA Commissioner Scott Gottlieb announced earlier this year a new plan for modernizing FDA's dietary supplement regulation and oversight. This followed the creation just three years ago of FDA's Office of Dietary Supplement Programs. The Department of Justice also has recognized the need for greater action against abuses in the dietary supplement space—it is just common sense that there will be fraud where you have a combination of high profits, developing science, imported ingredients, and limited oversight.

So, what have we done? In 2019, the Consumer Protection Branch secured criminal convictions against 15 individuals and corporations for defrauding consumers about the ingredients in and uses of their dietary supplements. Concluding a prosecution that drew much attention when initiated, the Branch secured felony guilty pleas from the five leading defendants and two corporate defendants in the *USP Labs* case. The defendants, who collectively agreed to pay $60 million in forfeiture and face years of imprisonment, each admitted to participating in a conspiracy to import dietary supplement ingredients using false certificates of analysis and labeling. They also admitted to misleading customers about the source and

nature of their ingredients—claiming they derived from natural plant extracts when they actually contained a synthetic stimulant manufactured in a Chinese chemical factory.

Similarly, we successfully prosecuted three Chinese nationals and two companies in connection with another fraud and smuggling scheme to sell mislabeled dietary supplements containing hidden synthetic stimulants. And we recently indicted six individuals and two companies for allegedly selling dietary supplements that contained ingredients—including anabolic steroids—they knew were dangerous or illegal. That indictment is notable because it contains the first-ever charges under the Designer Anabolic Steroid Control Act of 2014.

On top of these criminal actions, we also used our civil tools to enjoin various supplement manufacturers and distributors who were making unapproved new drug claims about their products and failing to adhere to current good manufacturing practices, which are essential to ensuring that supplements contain what is promised and are not adulterated. We share the FDA's concern that the making of unapproved new drug claims risks causing consumers to forego approved and more appropriate medical treatments, leading to predictable patient harm.

You can expect DOJ to increase its resources devoted to investigating and litigating in this area. Indeed, the Consumer Protection Branch will add 6 new attorneys soon just to focus on such efforts. We will coordinate our work with FDA and other partners—including, notably, the Department of Defense, which is concerned about servicemembers' use of adulterated supplements. By rooting out baseless efficacy claims and undeclared ingredients, we hope that our work will benefit the many legitimate

supplement manufacturers who are complying with the law and, most importantly, will keep consumers safe.

B. Opioids

Now, no review of enforcement in the food and drug world would be complete without a discussion of the Department's broad efforts to stem the prescription opioid crisis, which unfortunately still has a stranglehold on this country. As a leading component of the Department's Prescription Interdiction and Litigation—or PIL—Task Force, the Consumer Protection Branch is at the center of those efforts, advancing cases against opioid manufacturers, distributors, and chain pharmacies.

Over the summer, global consumer goods conglomerate Reckitt Benckiser Group agreed to pay $1.4 billion to resolve its criminal and civil liability related to a federal investigation into the marketing of the opioid addiction treatment drug, Suboxone. The resolution was the largest recovery by the United States in a case concerning an opioid drug. We also indicted Reckitt Benckiser Group's former subsidiary, Indivior Inc., for allegedly engaging in an illicit nationwide scheme to increase prescriptions of Suboxone. Trial in that case is set for May.

In addition to criminal actions, we have also routinely deployed a new tool this year—CSA civil injunctions—to take quick action to stop the illegal flow of prescription opioids. Dusting off a statutory provision that went virtually unused for 40 years, the Branch sought and obtained injunctions to stop the unlawful prescribing and dispensing of controlled substances. Consistent with Department policy and encouragement, we did much of this work in parallel with active criminal investigations and prosecutions. For instance, when DEA data showed that two pharmacies in a small Tennessee town were dispensing enough opioids to supply a city, we successfully enjoined the two pharmacies, their majority owner, and three pharmacists from continuing to dispense controlled substances. The

complaint also sought monetary penalties under the CSA and damages under the False Claims Act, and it was followed by criminal action against one of the pharmacists. You can look for CPB and its partners to bring many similar actions against a range of individuals and entities this coming year.

C. Misbranding Actions that Interfere with FDA's Mission

One of the most important cornerstones of our regulatory relationship with FDA is the guarantee that we will vigorously pursue those who interfere with FDA's mission of evaluating, approving, and regulating drugs and medical devices. These kinds of actions traditionally have included failure-to-report violations, interference with FDA, any number of misbranding offenses, false and misleading claims, and the misuse of manipulated or selectively chosen data. These actions all create a substantial risk of consumer harm.

In May, Hisao Yabe was sentenced for his failure to report information to FDA that called into question the safety of a medical scope manufactured by his employer, Olympus Medical Systems Corporation. Yabe was formerly the top regulatory official at the Japanese company, which also was convicted and ordered to pay $85 million in criminal fines and forfeiture. Yabe's and Olympus's convictions specifically concerned their failure to report that multiple patients at hospitals in Europe and the United States had experienced serious infections after being treated with an Olympus medical scope.

In June, ACell, Inc., a Maryland-based medical device manufacturer, similarly pleaded guilty to one misdemeanor count of failure and refusal to report a medical device removal to the FDA. In pleading guilty, ACell admitted that it failed to report that more than 30,000 of its MicroMatrix devices were contaminated with high levels of endotoxin, which posed a risk to patient health. ACell also admitted that it initiated a removal of those devices from sales representative inventories, hospitals, and other healthcare

centers, but did not notify FDA of the removal or of the endotoxin contamination. ACell further admitted that it did not notify doctors who already had purchased or used contaminated MicroMatrix devices about the removal.

Such actions interfere with FDA's essential functions—and put patients at risk and end up costing the responsible executives and companies far more in the long run than they save in the short term. The actions also were all caused by failures of corporate compliance programs.

D. Pharmacy Compounding

Some of you may have seen the piece on John Oliver's HBO show about compounding pharmacies. There was a lot to laugh at in that sketch, but, in reality, it highlighted a sector of the drug industry that has long been an area of concern for both FDA and CPB. The Consumer Protection Branch and our partners have a long history of successful enforcement against problematic compounding pharmacies—and 2019 was no different.

People working in this space know where our focus is: we look to enforce against facilities that put patients at risk through repeated violations of the insanitary conditions provisions under section 351 of the FDCA. Such conditions may include circumstances under which contamination or injury *may* occur—but neither we nor FDA will wait until harm *does* occur to act. Compounders who don't take their mission seriously, especially those making sterile injectable products, should thus not be surprised when FDA and CPB visit them with an inspection, an injunction, or a grand-jury subpoena.

Two actions in 2019 show the breadth and depth of CPB's commitment in this area. In the first, CPB obtained a consent decree of permanent injunction against the massive outsourcing compounding

pharmacy PharMedium, along with two of its executives, to stop its manufacturing, holding, and distribution of drugs from its Tennessee facility until remedial measures are taken. Our complaint alleged that PharMedium's drugs were adulterated because of insanitary conditions and because PharMedium failed to comply with current good manufacturing practices.

In the second action, we secured the conviction of Paul Elmer, who operated a drug compounding pharmacy called Pharmakon in Noblesville, Indiana. Trial evidence showed that Pharmakon routinely shipped sterile, intravenous drugs to hospitals without having received laboratory test results to verify that the drugs matched their stated strengths. Evidence also showed that, despite later receiving laboratory test results showing potency failures, Elmer did not recall over- or under-potent drugs; notify the FDA of the potency failures; or conduct any investigation to determine the cause of the potency failures. His actions led to several infants nearly dying after being injected with 2000x super-potent morphine—and he is now in jail.

E. Vaping

I'll conclude my review of 2019 enforcement highlights with a discussion of vaping. The outbreak of severe lung injuries related to vaping products has led to a national health crisis that threatens Americans, including many younger Americans. To date, the CDC has reported 2,051 injuries and 39 deaths related to vaping products. While the CDC and FDA continue to investigate the cause of the outbreak as a public health issue, they have raised a particular concern about vaping products containing THC. In line with that concern, CPB and a bevy of law enforcement partners are advancing actions across the country concerning the importation,

distribution, and sale of counterfeit, misbranded, and adulterated THC vaping products and paraphernalia.

These actions are already producing results, with an indictment secured this month in Dallas and numerous search warrants executed that promise to help us stop individuals who are selling poison dressed up as a carefree product. More work here will continue.

In addition, our Branch will be prepared to take appropriate action against adulterated and misbranded electronic nicotine delivery system products, and to defend the FDA's efforts to halt the rise in harmful teen vaping.

III. New Tools and Approaches

Having reviewed where the Consumer Protection Branch has been and where we're going with enforcement, I'd like to take a few minutes now to discuss how we are getting there. In short, we are aiming to progress more intelligently and more predictably. We will proceed more intelligently by using data analytics, enforcement discretion, and a wider range of tools. And we will seek greater predictability by keeping in view the principles in the new Executive Orders on agency guidance and enforcement, and application of a consistent policy on the assessment and crediting of corporate compliance policies.

A. Target Selection / Enforcement Discretion

Law enforcement is undergoing a transformation. For the first time ever, we are consistently able to advance enforcement initiatives *proactively*, rather than just *reacting* to whatever leads may come our way. The ability to analyze large subsets of data and documents has made this possible. Instead of agents conducting investigations based on leads and then bringing whatever cases they may develop to a prosecutor, we are able to have agents

and prosecutors work in tandem at the outset to spot outliers and significant subjects for investigation. Data from Customs, FDA, DEA, CMS, SSA, DoD, FTC, and the rest of the alphabet agencies makes this possible—in conjunction with sophisticated analytical tools. The Consumer Protection Branch is at the cutting edge of the effort to initiate and develop investigations intelligently through data analytics.

As new tools improve our ability to select and advance those investigations that involve the greatest elements of consumer harm and deception, we also are seeking to exercise our enforcement discretion more robustly to avoid matters that lack those elements. In addition, we are now utilizing a greater range of options in seeking appropriate resolutions. In some instances—like the non-prosecution agreement reached with Reckitt Benckiser Group—this means accepting unique resolution terms; in others, it can mean using a civil remedy over a criminal remedy, or talking first and threatening suit second. CPB's pioneering use of civil injunctions in the CSA space is an example of this in action. We are able with those injunctions to take quick action to achieve the primary goal of stopping overdose deaths without prejudicing our ability to later use a criminal tool for other ends. Our belief is that reasonable employment of such enforcement approaches makes us more credible, efficient, and effective.

B. EOs on Guidance and Enforcement

In addition to being smarter in our enforcement of priority initiatives, we also are aiming to be consistent and adherent to basic rule-of-law principles. The October 2019 Executive Orders on agency guidance and enforcement are helpful to that effort. The Executive Orders are designed to prevent unfair surprise and to ensure that agency guidance does not become a back-door means of regulation.

Violations of law should be based on statutes and regulations enacted with proper notice and comment. As President Trump noted when issuing

the Executive Orders, however, many federal agencies have issued thousands of guidance documents. And instead of serving their intended purpose—guidance—the documents often morph into requirements used to assign liability.

To be sure, the Department of Justice's long-standing policy has been to bring enforcement litigation only for violations of federal statutes and their attending regulations. Nothing there has changed and the Department may still take enforcement action consistent with agency policy statements—including FDA's Compliance Policy Guidelines—so long as those statements are not the sole basis for enforcement and are firmly based in a statute or regulation. The goal is to prevent surprise and ensure that laws and formal rulemaking controls.

Consistent with the principles set forth in the Executive Orders, CPB will consider notice and process in making decisions throughout the investigative and litigation phases of matters. This will help to ensure that while we continue to protect consumer safety, we do so consistent with basic notions of fairness and due process.

C. Compliance

Finally, I'll say a few words about compliance programs. Compliance programs matter. Given that you all are here at this conference, I expect you already know that. But it's true. A good compliance program can keep a company out of trouble and help make a resolution possible if it nevertheless finds itself there.

In many respects, those of us who practice under the FDCA should seemingly have a leg up when it comes to compliance. Our guiding statute and the regulatory scheme that accompanies it are founded on the notion that more than just profits are at stake. Our stock in trade is human health, safety, and welfare, and so the FDCA in many ways should make us more

adept at crafting and adhering to compliance policies. At the same time, because of this background, the need and expectation for a compliance program is also greater in the FDCA context, where, as I mentioned, voluntary compliance with the law is essential.

For purposes of consistency within the Department—and because it makes good sense—the Consumer Protection Branch follows the same principles as the Department's Criminal Division in assessing compliance programs for charging and resolution purposes. Key to those principles is the idea that companies can expect the Department to decline to prosecute if they timely report wrongdoing, cooperate fully, and remediate adequately. That is a substantial idea and one consistent with CPB's desire to smartly and fairly conduct its work. Obviously the idea requires a fact-specific analysis of each case, and it offers benefit only if a company has enough of a compliance system to identify and report a problem in the first place. But it should be a helpful motivator to take compliance seriously and realize that a call from you to us is better than a call from us to you.

IV. Conclusion

I will end by thanking you for your work to make peoples' lives better. The products you manufacturer and support are extraordinary, and we are all grateful for them. By diligently and smartly enforcing the law, we at the Consumer Protection Branch strive to support you in your work while safeguarding Americans from those who would risk their harm for gain.

With that, I thank you.