



ADMINISTRATION'S WHITE PAPER ON INTELLECTUAL PROPERTY ENFORCEMENT LEGISLATIVE RECOMMENDATIONS



MARCH 2011





INTRODUCTION

On June 22, 2010, the U.S. Intellectual Property Enforcement Coordinator (IPEC) issued the Administration's first Joint Strategic Plan on Intellectual Property Enforcement (Strategy), which was developed in coordination with many Federal agencies, including the Departments of Commerce, Health and Human Services, Homeland Security (DHS), Justice (DOJ), and State, and the U.S. Trade Representative. As part of the Strategy, the Administration undertook to review existing laws to ensure that they were effective and to identify deficiencies that could hinder enforcement. Based on that review, this White Paper identifies specific recommended legislative changes, designed to increase the effectiveness of U.S. enforcement efforts. We will, of course, continue to assess existing legislation and recommend any further changes to the law as the need arises.

Piracy and counterfeiting in the online environment are significant concerns for the Administration. They cause economic harm and threaten the health and safety of American consumers. Foreign-based and foreign-controlled websites and web services raise particular concerns for U.S. enforcement efforts. We are aware that members of Congress share our goal of reducing online infringement and are considering measures to increase law enforcement authority to combat websites that are used to distribute or provide access to infringing products. We look forward to working with Congress on those efforts and the recommendations contained in this paper in the coming year.

Turning to the specific recommendations, the Administration recommends increasing the statutory maxima for the following offenses:

1. Increase the statutory maximum for economic espionage (18 U.S.C. § 1831) from 15 years in prison to at least 20 years in prison; and
2. Increase the statutory maxima for drug offenses under the Federal Food, Drug and Cosmetic Act (FFDCA), particularly for counterfeit drug offenses.

The Administration recommends that Congress: (1) direct the U.S. Sentencing Commission to increase the U.S. Sentencing Guideline range for intellectual property offenses; (2) require the U.S. Sentencing Commission to consider five specific categories of changes to the Guidelines; and (3) require the U.S. Sentencing Commission to act within 180 days of such legislation being adopted (including issuing a report explaining why it has not adopted any of the specific recommendations). The five categories of specific recommendations for the U.S. Sentencing Commission are:

1. Increase the U.S. Sentencing Guideline range for the theft of trade secrets and economic espionage, including trade secrets transferred or attempted to be transferred outside of the U.S.;
2. Increase the U.S. Sentencing Guideline range for trademark and copyright offenses when infringing products are knowingly sold for use in national defense, national security, critical infrastructure, or by law enforcement.
3. Increase the U.S. Sentencing Guideline range for intellectual property offenses committed by organized criminal enterprises/gangs;

4. Increase the U.S. Sentencing Guideline range for intellectual property offenses that risk death or serious bodily injury and for those offenses involving counterfeit drugs (even when those offenses do not present that risk); and
5. Increase the U.S. Sentencing Guideline range for repeat intellectual property offenders.

The Administration recommends three legislative changes to give enforcement agencies the tools they need to combat infringement:

1. Clarify that, in appropriate circumstances, infringement by streaming, or by means of other similar new technology, is a felony;
2. Authorize DHS, and its component U.S. Customs and Border Protection (CBP), to share pre-seizure information about, and samples of, products and devices with rightholders to help DHS to determine whether the products are infringing or the devices are circumvention devices; and
3. Give law enforcement authority to seek a wiretap for criminal copyright and trademark offenses.

The Administration recommends two legislative changes to allow DHS to share information about enforcement activities with rightholders:

1. Give DHS authority to notify rightholders that infringing goods have been excluded or seized pursuant to a U.S. International Trade Commission (ITC) order; and
2. Give DHS authority to share information about, and samples of, circumvention devices with rightholders post-seizure.

The Administration recommends six legislative changes to improve U.S. enforcement efforts involving pharmaceuticals, including counterfeit drugs:

1. Require importers and manufacturers to notify the Food and Drug Administration (FDA) and other relevant agencies when they discover counterfeit drugs or medical devices, including the known potential health risks associated with those products;
2. Extend the Ryan Haight Act's definition of "valid prescription" (and its telemedicine exemption) to the FFDCRA to drugs that do not contain controlled substances;
3. Adopt a track-and-trace system for pharmaceuticals and related products;
4. Provide for civil and criminal forfeiture under the FFDCRA, particularly for counterfeit drug offenses;
5. As noted above, increase the statutory maxima for drug offenses under the FFDCRA, particularly for counterfeit drug offenses; and
6. As noted above, recommend that the U.S. Sentencing Commission increase the U.S. Sentencing Guideline range for intellectual property offenses that risk death and serious bodily injury, and for those offenses involving counterfeit drugs (even when those offenses do not present that risk).

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The Administration recommends three legislative changes as to CBP's administrative penalties:

1. Permit relief when someone who unknowingly and unintentionally acquires infringing products voluntarily discloses them to CBP before becoming aware of any CBP enforcement action (or a law enforcement investigation);
2. Give CBP authority to issue penalties for infringing exports; and
3. Strengthen CBP's authority to issue penalties for infringing imports discovered during audits of company records.

Finally, the Administration recommends a legislative change to provide a right of public performance that will improve international enforcement efforts:

1. Create a right of public performance for copyright owners for sound recordings transmitted by over-the-air broadcast stations which, in part, will allow copyright owners to obtain overseas royalties that are now denied to them.



Increase Existing Criminal Penalties

Increase Intellectual Property Statutory Maxima

Increase the Statutory Maximum for Economic Espionage: Economic espionage is one of the most serious intellectual property crimes. A defendant committing that offense, however, faces a statutory maximum sentence of only 15 years in prison. 18 U.S.C. § 1831(a). We recommend that Congress raise that statutory maximum given the severity of the conduct inherent in the offense. Other non-intellectual property offenses that have higher statutory maxima include mail fraud (20 years; 18 U.S.C. § 1341), bank fraud (30 years; 18 U.S.C. § 1344), smuggling goods into the U.S. (20 years; 18 U.S.C. § 545), and counterfeit U.S. currency offenses (20 years; 18 U.S.C. §§ 471, 472, 473). Moreover, under the U.S. Sentencing Guideline that applies to economic espionage, U.S. Sentencing Guideline (USSG) § 2B1.1, an offense with a statutory maximum sentence of 20 years or more in prison triggers a base offense level of seven, as opposed to the base offense level of six triggered by an offense with a statutory maximum sentence of less than 20 years in prison. USSG §§ 2B1.1(a)(1), (a)(2). Increasing the statutory maximum to at least 20 years in prison, thereby triggering the higher base offense level, is appropriate for this serious offense.

Recommendation: The Administration recommends that Congress increase the statutory maximum sentence for economic espionage to at least 20 years in prison.

Increase the Statutory Maxima under the FFDCA: The FFDCA prohibits, among other offenses, adulterated, misbranded, and counterfeit pharmaceuticals. Most criminal violations of the FFDCA, however, are subject to statutory maxima of no more than three years in prison. For example, counterfeit pharmaceutical cases prosecuted under 21 U.S.C. § 331(i) are generally misdemeanors, 21 U.S.C. § 333(a)(1), unless the government proves that the defendant committed the offense with the intent to defraud or mislead, 21 U.S.C. § 333(a)(2). In such circumstances, the offense becomes a felony, but one subject only to a statutory maximum sentence of three years in prison. *Id.* This contrasts with the 10-year statutory maximum for the sale of products with counterfeit trademarks (including for drugs) under 18 U.S.C. § 2320. The Administration recommends that Congress increase the statutory maxima for drug offenses under the FFDCA, particularly for counterfeit drug offenses.

Recommendation: The Administration recommends that Congress increase the statutory maxima under the FFDCA, particularly for counterfeit drugs.

Legislation Requiring the U.S. Sentencing Commission to Consider Increases to the Guideline Range Based on Aggravated Offense Conduct in Intellectual Property Cases

According to DOJ's 2009 and 2010 PRO-IP Act reports to Congress, from Fiscal Year 2004 through 2010 — a period of seven years — less than half (762) of the defendants sentenced for intellectual property

crimes (1,469) received prison time as part of their sentence. To help ensure that the penalties for intellectual property crimes match the harm caused by those offenses, the Administration considered a number of increases to intellectual property crime statutory maxima based on aggravated offense conduct. The Administration believes that Congress can effectively address the harm caused by this conduct by directing the U.S. Sentencing Commission to amend the theft of trade secret and economic espionage U.S. Sentencing Guideline (USSG § 2B1.1) and the copyright and trademark infringement Guideline (USSG § 2B5.3).

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission that it shall: (1) amend the theft of trade secret and economic espionage U.S. Sentencing Guideline (USSG § 2B1.1) and the copyright and trademark infringement Guideline (USSG § 2B5.3) to increase the Guideline ranges applicable to those offenses, so as to more effectively address the substantial harm caused by intellectual property crimes; (2) consider, among other possible increases, the following five categories of recommended increases to the Guidelines (described below); and (3) complete its consideration/review within 180 days of the date of enactment of the legislation and, if it chooses not to adopt any of the specific recommendations, within that 180 days, the U.S. Sentencing Commission shall issue a report explaining why it has not adopted the recommendation(s).

Increase in the Offense Level for Theft of Trade Secrets and Economic Espionage: There is currently a two-level enhancement for economic espionage: “If the offense involved misappropriation of a trade secret and the defendant knew or intended that the offense would benefit a foreign government, foreign instrumentality, or foreign agent, increase by 2 levels.” USSG § 2B1.1(b)(5). The Administration recommends that Congress adopt legislation requiring the U.S. Sentencing Commission to consider three changes to this Guideline. First, the two-level enhancement should apply to the simple misappropriation of a trade secret (the Guideline at issue is a general fraud Guideline and does not otherwise account for the theft of trade secrets). Second, an additional two-level enhancement should apply if the defendant transmits or attempts to transmit the stolen trade secret outside of the U.S., or an additional three-level enhancement should apply if the defendant instead commits economic espionage, *i.e.*, he/she knew or intended that the offense would benefit a foreign government, foreign instrumentality, or foreign agent. Third, when a defendant transmits trade secrets outside of the U.S. or commits economic espionage, that defendant should face a minimum offense level.

These three changes will help make the sentences for the theft of trade secrets — particularly those involving economic espionage — more appropriately reflect the harm caused by the criminal conduct. Moreover, adopting a two-level enhancement for the theft of trade secrets would make the offense level (absent other aggravated conduct) the same for trade secret, copyright, and trademark offenses. That is so, because trade secret offenses start with a two-level lower base offense level under USSG § 2B1.1(a)(2) (six) than do copyright and trademark offenses under USSG § 2B5.3(a) (eight).

We note that we have only recommended an additional one-level enhancement when a defendant steals trade secrets to commit economic espionage, as opposed to transfers of trade secrets outside of the U.S. We recommend only an additional one-level enhancement, rather than a two-level increase because,

if Congress adopts our recommendation to increase the statutory maximum for economic espionage to at least 20 years in prison, the base offense level for economic espionage will be one level higher (seven) than for the theft of trade secrets (six). Accordingly, with an additional one-level enhancement for economic espionage, someone committing that offense would actually have an offense level two levels higher than someone who stole trade secrets and transferred or attempted to transfer them outside of the U.S. We, thus, believe that the additional, one-level enhancement addresses the aggravated harm from economic espionage (over and above the theft and transfer or attempt to transfer trade secrets outside the U.S.).

Finally, we have recommended that, when a defendant transmits or attempts to transmit trade secrets outside of the U.S. or commits economic espionage, that defendant should face a minimum offense level. The Guideline at issue (USSG § 2B1.1) is largely based on loss, with a significant prison sentence resulting when the loss or intended loss from the theft of the trade secret is significant. But, even where there is little loss or the government is unable to prove a significant loss, there is inherent aggravated harm in transferring or attempting to transfer trade secrets outside of the U.S. or in committing economic espionage. Without a minimum offense level, even with the changes above, a first time offender, with no other aggravated conduct and taking into account acceptance of responsibility, will face a Guideline range of only: (1) 0-6 months in prison for transferring or attempting to transfer trade secrets outside the U.S.; and (2) 6-12 months in prison for economic espionage. These Guideline ranges do not properly account for the aggravated harm inherent in such offense conduct. The Administration, thus, recommends that the U.S. Sentencing Commission study and adopt an appropriate minimum offense level for this conduct.

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing: (1) a two-level enhancement for theft of trade secrets; (2) an additional two-level enhancement if the defendant transmits or attempts to transmit trade secrets outside of the U.S. or an additional three-level enhancement if the defendant instead commits economic espionage; and (3) a minimum offense level when the defendant transmits or attempts to transmit trade secrets outside of the U.S. or commits economic espionage.

Increase in the Offense Level for Infringing Products Knowingly Sold for Defense, Military, Law Enforcement, or Other Critical Uses: There is currently no Guideline enhancement if a defendant sells infringing products to, or for use by, the military or law enforcement or for use in critical infrastructure. This criminal conduct, however, jeopardizes the safety of those serving in the U.S. military, those serving in law enforcement, and the public as a whole. This significantly aggravated criminal conduct deserves a significantly increased criminal sentence. The Administration recommends that Congress direct the U.S. Sentencing Commission to consider adopting the following enhancement: "If the defendant knew the offense involved a critical infrastructure or product sold for use in national defense or national security or by law enforcement, increase by four levels. If the resulting offense level is less than level 14, increase to level 14." With a minimum offense level of 14, a first-time offender with no criminal history will face

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at least a 10-16 month Guideline range without any other aggravated conduct (taking into account a reduction for acceptance of responsibility).

The Administration also recommends adding an application note to the provision to ensure that sales that only indirectly impact national defense or security, law enforcement functions, or critical infrastructure are not swept into the provision. Thus, a sale of counterfeit semiconductors for use in a military system qualifies for the enhancement; the sale of a counterfeit toner cartridge for a computer printer used at military headquarters would ordinarily not.

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing a four-level enhancement (and a minimum offense level of 14) for copyright and trademark offenses involving products knowingly sold for use in critical infrastructure, national defense, national security, or by law enforcement.

Increase in the Offense Level for Intellectual Property Crimes Involving Gangs/Organized Criminal Enterprises: Intellectual property infringement is a strong lure to organized criminal enterprises, which could use infringement as a revenue source to fund their other unlawful activities. That is so, because intellectual property infringement can involve a potentially high profit margin while risking a shorter prison sentence than other criminal offenses, such as trafficking drugs. U.S. Sentencing Guideline Section 2B5.3 does not currently provide an enhancement if the offense was committed by, or for the benefit of, organized criminal enterprises, although it does suggest that an upward departure may be appropriate if “[t]he offense was committed in connection with, or in furtherance of, the criminal activities of a national, or international, organized criminal enterprise.” USSG § 2B5.3 comment. (n.4(B)). Similarly, the Guidelines suggest that an upward departure may be appropriate if the offense involved violent criminal street gangs. USSG § 5K2.18. Rather than provide optional departures, the Administration recommends that Congress direct the U.S. Sentencing Commission to consider up to a four-level enhancement “[i]f the offense was committed in connection with, or in furtherance of, the criminal activities of a local, national, or international organized criminal enterprise.” We believe that this recommendation more appropriately reflects the significant aggravated harm in such circumstances.

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing up to a four-level enhancement for intellectual property offenses involving gangs/organized criminal enterprises.

Increase in the Offense Level for Counterfeit Drug Cases and Cases Presenting a Serious Risk to Health: The sale of counterfeit pharmaceuticals is a significant problem, including the sale of counterfeit drugs containing potentially dangerous chemicals or lacking the ingredients needed to treat serious medical conditions. U.S. Sentencing Guideline Section 2B5.3(b)(5) provides: “If the offense involved

(A) the conscious or reckless risk of death or serious bodily injury; or (B) possession of a dangerous weapon (including a firearm) in connection with the offense, increase by 2 levels. If the resulting offense level is less than level 14, increase to level 14.” The Administration recommends two changes to this existing Guideline.

First, where there is a “conscious or reckless risk of death or serious bodily injury,” that significantly aggravated conduct should warrant a significantly increased sentence. The Administration, thus, recommends increasing the current enhancement by two levels when there is “conscious or reckless risk of death or serious bodily injury,” such that there would be a four-level enhancement. The Administration recommends retaining the current minimum offense level of 14.

Second, there are inherent risks associated with counterfeit drugs that are not accounted for under this Guideline and that warrant an enhanced sentence even where a defendant does not recklessly risk serious bodily injury. Accordingly, a defendant selling counterfeit pharmaceuticals should automatically receive a two-level enhancement (even where there is no conscious or reckless risk of death or serious bodily injury). Where a defendant has no other aggravated conduct (taking into account a reduction for acceptance of responsibility), this two-level increase does not actually raise the Guideline range: It is 0-6 months in prison with a base offense level of 8 (minus two points for acceptance of responsibility) and after the two-level enhancement (10 minus those same two points). Accordingly, the Administration recommends that the U.S. Sentencing Commission consider a minimum offense level of 12 for offenses involving counterfeit drugs. With that minimum offense level, a first-time offender with no criminal history will face a 6-12 month Guideline range without any other aggravated conduct (taking into account a reduction for acceptance of responsibility).

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing: (1) a four-level enhancement for offenses involving the conscious or reckless risk of death or serious bodily injury; and (2) a two-level enhancement, and a minimum offense level of 12, for offenses involving counterfeit pharmaceuticals (where there is no conscious or reckless risk of death or serious bodily injury).

Increase in the Offense Level for Recidivist Intellectual Property Offenders: U.S. Sentencing Guideline Section 2B5.3 does not currently provide an enhancement to a defendant who committed a second or subsequent intellectual property offense, even though Congress has doubled the statutory maximum for recidivist intellectual property offenders. See, e.g., 18 U.S.C. §§ 2319(b)(2),(c)(2),(d)(3),(d)(4) (doubling the statutory maxima for recidivist copyright offenses); 18 U.S.C. § 2320(a)(1) (doubling the statutory maximum for recidivist trademark offenses). Some other Guideline provisions take recidivist conduct into account when calculating the offense level. See USSG § 2N2.1(b)(1) (four-level enhancement for a conviction under 21 U.S.C. § 331 if the defendant had a previous conviction under that section); see also USSG §§ 2D1.1(a)(1),(a)(3) (increased base offense level where, among other factors, the defendant committed the offense “after one or more prior convictions for a similar offense”); § 2L1.1(b)(3) (enhancements for smuggling, transporting, or harboring aliens when the defendant had previous immigration

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convictions); § 2L2.1(b)(4) (similar); § 2L2.2(b)(2) (similar), § 4B1.5 (increased offense level for repeat sex offenders).¹ To appropriately increase the punishment for recidivist intellectual property offenders, we recommend that Congress direct the U.S. Sentencing Commission to consider imposing a two-level enhancement when a defendant has a previous intellectual property conviction (either under Federal or state law, whether the conviction was a misdemeanor or a felony, and regardless of the type of the previous intellectual property offense).

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider providing a two-level enhancement for defendants with a previous conviction for an intellectual property offense.

1. See USSG § 2B1.5(b)(5) (enhancement for pattern of misconduct involving cultural heritage resources); § 2G2.2(b)(5) (enhancement for pattern of sexual abuse or exploitation of minors); § 2Q2.1(b)(1)(B) (enhancement for pattern of wildlife offenses); see, e.g., USSG §§ 2K1.3(a)(1),(a)(2) (increased base offense level for explosive material offenses if the defendant had prior convictions for crimes of violence or controlled substances); §§ 2K2.1(a)(1)-(a)(4) (increased base offense level for firearm offenses if the defendant had prior convictions for crimes of violence or controlled substances), § 2L1.2(b) (enhancements for aliens illegal returning to the U.S. after being deported and sustaining various convictions), § 4B1.1 (increased offense level for career offenders), § 4B1.4 (similar).



Providing Enforcement Agencies the Tools They Need to Discover and Combat Infringement

Ensure Felony Penalties for Infringement By Streaming and by Means of Other New Technology: It is imperative that our laws account for changes in technology used by infringers. One recent technological change is the illegal streaming of content. Existing law provides felony penalties for willful copyright infringement, but felony penalties are predicated on the defendant either illegally reproducing or distributing the copyrighted work.² Questions have arisen about whether streaming constitutes the distribution of copyrighted works (and thereby is a felony) and/or performance of those works (and thereby is not a felony). These questions have impaired the criminal enforcement of copyright laws. To ensure that Federal copyright law keeps pace with infringers, and to ensure that DOJ and U.S. law enforcement agencies are able to effectively combat infringement involving new technology, the Administration recommends that Congress clarify that infringement by streaming, or by means of other similar new technology, is a felony in appropriate circumstances.

Recommendation: The Administration recommends that Congress clarify that infringement by streaming, or by means of other similar new technology, is a felony in appropriate circumstances.

Give DHS Authority to Share Information with Rightholders Pre-Seizure to Help Determine Whether Products Are Infringing or Devices Are Circumvention Devices: Obtaining the assistance of rightholders pre-seizure to help determine whether goods are infringing is important. Rightholders know their products better than anyone else and, thus, obtaining their assistance allows DHS, particularly its component CBP, to more effectively identify and combat infringing products. There are concerns, however, that sharing unredacted samples of products and its packing with a rightholder pre-seizure would violate the Trade Secrets Act, 18 U.S.C. § 1905. In the Joint Strategic Plan, the Administration committed to providing DHS with express authority to share such information pre-seizure. The Administration recommends legislation giving DHS that authority, with any appropriate safeguards for importers importing legitimate products.

Similarly, it is illegal to import or traffic in devices that can be used to circumvent technological measures that control access to copyrighted works. When DHS discovers the importation of a potential circumvention device, current law does not authorize DHS to share a sample with a rightholder to aid CBP in determining whether it is, in fact, a circumvention device. Allowing DHS to provide a sample would aid enforcement efforts. In the Joint Strategic Plan, the Administration committed to providing DHS with that authority and the Administration recommends legislation giving DHS that authority.

2. See 17 U.S.C. § 506(a)(1)(A) (offense), 18 U.S.C. § 2319(b)(1) (felony for specified “reproduction or distribution”); 17 U.S.C. § 506(a)(1)(B) (“reproduction or distribution” offense), 18 U.S.C. § 2319(c)(1) (felony for specified “reproduction or distribution”); 17 U.S.C. § 506(a)(1)(C) (pre-release “distribution” offense), 18 U.S.C. § 2319(d)(1) (felony penalty).

Recommendation: The Administration recommends that Congress authorize DHS to: (1) share information about, or unredacted samples of, products and/or their packaging with rightholders pre-seizure to aid in determining whether goods are infringing (subject to any bonding requirement and any appropriate safeguards for importers of legitimate products); and (2) share samples of potential circumvention devices pre-seizure to aid in determining whether they are, in fact, circumvention devices (subject to any bonding requirement).

Give Wiretap Authority for Criminal Copyright and Trademark Offenses: The Joint Strategic Plan committed Federal agencies to identify gaps in current intellectual property laws and ways that the U.S. Government could enhance enforcement. One such gap involves wiretapping authority (that is, authority to intercept wire, electronic, and/or oral communications). Title 18, United States Code, Section 2516 contains an extensive list of offenses for which the U.S. Government is authorized to seek wiretap authority from a court to obtain evidence of those offenses, including for economic espionage (18 U.S.C. § 1831) and theft of trade secrets (18 U.S.C. § 1832). See 18 U.S.C. § 2516(1)(a) (listing offenses under chapter 90). Omitted from this list are criminal copyright (17 U.S.C. § 506(a)(1), 18 U.S.C. § 2319) and criminal trademark offenses (18 U.S.C. § 2320). Wiretap authority for these intellectual property crimes, subject to the existing legal protections that apply to wiretaps for other types of crimes, would assist U.S. law enforcement agencies to effectively investigate those offenses, including targeting organized crime and the leaders and organizers of criminal enterprises.

Recommendation: The Administration recommends that Congress amend 18 U.S.C. § 2516 to give law enforcement authority to seek a wiretap for criminal copyright and trademark offenses.



Enhance Information Sharing About Enforcement Activity

Ordinarily, DHS is able to inform rightholders after infringing goods have been seized, which can help rightholders to enforce their own rights, including bringing a civil suit, if appropriate. The Administration has identified two areas in which DHS is not expressly authorized to share information post-seizure.

Give DHS Authority to Share Information with Rightholders About Seizures and Exclusions Pursuant to an ITC Order: Under 19 U.S.C. § 1337, the ITC investigates allegations regarding unfair importation practices, including those involving intellectual property infringement. Once the ITC finds a violation and issues an order barring the importation of infringing goods, DHS, through its component CBP, is responsible for enforcing that order at the border. DHS currently lacks express authority to notify rightholders that goods have been excluded or seized under an ITC order. Giving rightholders that information will aid them in combating infringement. In the Joint Strategic Plan, the Administration committed to providing DHS with authority to share this information.

Recommendation: The Administration recommends that Congress give DHS authority to notify rightholders that infringing goods have been excluded or seized pursuant to an ITC order.

Give DHS Express Authority to Share Information with Rightholders About Circumvention Devices: After DHS has seized a circumvention device, current law does not expressly give DHS authority to share that information with rightholders or to provide a sample of the device. Allowing DHS to provide both, however, would assist rightholders in protecting their copyrighted work by, among other possibilities: (1) allowing them to alter the technological control to render the circumvention devices ineffective; (2) assisting them in investigating infringement of their intellectual property rights; and (3) assisting them in bringing civil actions to enforce their intellectual property rights. In the Joint Strategic Plan, the Administration committed to providing DHS and its components with authority to share such information and samples, which is what DHS already does for trademark and copyright seizures.

Recommendation: The Administration recommends that Congress authorize DHS to inform rightholders when circumvention devices are seized and to provide samples of such devices (subject to any DHS bonding requirement).



Combat Counterfeit Drugs

Notification When Importers and Manufacturers Discover Counterfeit Drugs and Medical Products:

Counterfeit drugs threaten public health and, when they are discovered by importers or manufacturers, the importers or manufacturers should notify the FDA and other relevant agencies, including any known potential health risks, thereby allowing the FDA or other agencies to take action. Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) have already voluntarily agreed to provide notification to the FDA. That disclosure, however, does not include all manufacturers, nor does it necessarily include importers. In the Joint Strategic Plan, the Administration recognized the need for such notification and the Administration recommends adopting legislation providing for such notification.

Recommendation: The Administration recommends that Congress require importers and manufacturers to notify the FDA and other relevant agencies when they discover counterfeit drugs or medical products, including the known health risks associated with them.

Extend the Ryan Haight Act’s Definition of “Valid Prescription” (and Telemedicine Exemption) to the FFDCA to Apply to Drugs that Do Not Contain Controlled Substances:

Online pharmacies that are least likely to enforce prescription requirements are also generally most likely to sell counterfeit drugs.

The Controlled Substances Act prohibits the distribution of controlled substances without a valid prescription and, significantly, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act) provides, for the first time, a Federal definition of “valid prescription.” Public Law 110-425, 122 Stat. 4820, § 2 (2008). Under that definition, a prescription is only valid if it has been issued by a practitioner who has conducted an “in-person medical evaluation” or by a covering practitioner (although an exemption is included in the Ryan Haight Act for prescriptions issued by a practitioner engaged in the legitimate practice of telemedicine). The Ryan Haight Act also codified regulatory language (21 C.F.R. § 1306.04(a)) that requires the prescription to be issued for a “legitimate medical purpose in the usual course of professional practice.” The definition was designed to address the practice of online pharmacies that dispensed controlled substances without a prior prescription or on the basis of a purported review by a physician who reviewed a questionnaire.

Many online pharmacies sell prescription drugs that do not contain controlled substances. The FFDCA regulates such sales, requiring a “practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1). There is, however, no definition of what constitutes a valid prescription under this Act and, thus, no definition that applies to prescription drugs that do not contain controlled substances. The Administration recommends amending the FFDCA (21 U.S.C. § 353(b)(1)) to use the definition of valid prescription in the Ryan Haight Act (and also to use its exemption for prescriptions issued through the legitimate practice of telemedicine). By making that amendment, Congress can help reduce the number of online pharmacies evading prescription requirements and, in turn, selling counterfeit drugs.

Recommendation: The Administration recommends that Congress apply the Ryan Haight Act's definition of "valid prescription" to the FDCA to drugs that do not contain controlled substances (and incorporate an exemption for prescriptions issued through the legitimate practice of telemedicine).

Adoption of a Track-and-Trace System: Effective track-and-trace systems can make it more difficult to introduce counterfeit drugs into the U.S. market, make it easier to identify those responsible for making a product unsafe, and facilitate the recall of unsafe products by more quickly identifying where a product is located. In the Joint Strategic Plan, the Administration recommended the adoption of a track-and-trace system. We note the importance of addressing privacy concerns, such as deciding where the information resulting from this system will be housed and who will have access to it.

Recommendation: The Administration recommends that Congress adopt a track-and-trace system for pharmaceuticals and related products.

Provide for Forfeiture under FDCA: Title 18, United States Code, Section 2320(b) provides for civil and criminal forfeiture for counterfeit trademark offenses, as provided in 18 U.S.C. § 2323. The FDCA also prohibits, among other offenses, counterfeit trademark offenses involving pharmaceuticals, 21 U.S.C. § 331(i), but no such forfeiture authority exists under the FDCA. To make the FDCA consistent with other criminal statutes, particularly counterfeit trademark offenses under 18 U.S.C. § 2320, the Administration recommends providing forfeiture authority.

Recommendation: The Administration recommends that Congress give civil and criminal forfeiture authority under the FDCA, particularly for counterfeit drug offenses.

Increase the Statutory Maxima under the FDCA: As noted above, the Administration recommends that Congress increase the statutory maxima sentences under the FDCA, particularly for counterfeit drug offenses.

Recommendation: The Administration recommends that Congress increase the statutory maxima sentences under the FDCA, particularly for counterfeit drug offenses.

Increase the U.S. Sentencing Guideline Range in Counterfeit Drug Cases: As noted above, the Administration recommends that Congress direct the U.S. Sentencing Commission to consider increasing the Guideline range for counterfeit drug offenses, including a further enhanced penalty for such offenses involving the conscious or reckless risk of death or serious bodily injury.

COMBAT COUNTERFEIT DRUGS

Recommendation: The Administration recommends that Congress direct the U.S. Sentencing Commission to consider increasing the U.S. Sentencing Guideline range for counterfeit drug offenses, including a further enhanced penalty for such offenses involving the conscious or reckless risk of death or serious bodily injury.



Increase the Effectiveness of CBP Administrative Penalties

Provide Relief from Penalties for Voluntary Disclosure to CBP: In the Joint Strategic Plan, the Administration noted that there is no existing procedure for an importer or other party who unknowingly and unintentionally imported or acquired infringing products to voluntarily disclose them to CBP without being subject to seizure, penalties, and/or other enforcement actions. Allowing such voluntary disclosure is beneficial: It increases the destruction of infringing products and will potentially aid investigations into the source of those products.

Recommendation: The Administration recommends that Congress permit relief when someone who unknowingly and unintentionally acquires infringing products voluntarily discloses them to CBP before becoming aware of any CBP enforcement action (or becoming aware of a law enforcement agency investigation).

Authorize CBP to Issue Penalties for Infringing Exports: CBP can seize and forfeit infringing exports, but is not authorized to issue administrative penalties for infringing exports. Such administrative penalties would help serve as an effective deterrent to those exporting infringing products. Moreover, providing the ability to impose penalties for exporting infringing products would improve the U.S. Government's ability to advocate for other countries to impose penalties on those exporting infringing products into the U.S. In the Joint Strategic Plan, the Administration committed to seek legislation to give CBP such authority and the Administration, thus, recommends that Congress adopt such legislation.

Recommendation: The Administration recommends that Congress give CBP authority to issue penalties for the export of infringing products.

Give CBP Express Authority to Impose Penalties When an Examination of Records Demonstrates Previous Infringing Shipments: CBP has express authority to issue penalties only for infringing shipments that it seizes at the border. During post-entry audits of company records, however, CBP sometimes discovers evidence of infringing products previously imported into the U.S. Providing CBP express authority to establish violations, and thereby assess penalties, based on an examination of company records would help deter the importation of infringing products.

Recommendation: The Administration recommends that Congress give CBP authority to issue penalties for infringing imports discovered during audits of company records.



Public Performance Right for Sound Recordings

Ensure Copyright Owners Are Entitled to Compensation When Radio Stations Play Their Works:

Historically, in the U.S., there has been no right of public performance for sound recordings transmitted by over-the-air broadcast stations. The absence of such a right puts U.S. copyright owners at a disadvantage internationally. They are not permitted to collect overseas royalties because they are not granted rights in the U.S. The U.S. stands alone among industrialized nations in not recognizing a public performance right in sound recordings. The Administration recommends legislation giving sound recording owners that right.

Recommendation: The Administration recommends that Congress create a right of public performance for sound recordings transmitted by over-the-air broadcast stations.

