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2019-2020

Cryptocurrency: Legality and Role Within Us Financial Institutions

Casey Bessemer

Introduction

On March 6, 2018, the Eastern District of New York released their opinion for *CFTC v*. *McDonnell*, a case centered on the abuse of investors' trust using cryptocurrency."¹ The opinion is important for several reasons. First, it is one of the few cases that has involved the emerging cryptocurrency market. Second, it outlined a procedure to actually monitor and regulate the seemingly decentralized marketplace. Third, it raised a very important question: who, if anyone, will regulate cryptocurrency and how can they?²

Brief History of Cryptocurrency

Cryptocurrency came into the public eye in 2009, with the release of Bitcoin.³ The first ever cryptocurrency transaction, or "crypto-transaction," is believed to have taken place in Florida: when Laszlo Hanyecz a paid "10,000 bitcoins to get two pizzas delivered from Papa John's.⁴ Cryptocurrency provided an alternative to traditional currency for conducting business and investing. Where traditional currency is regulated by banks, who record and track currency by way of deposits and withdrawals, cryptocurrency provided a "peer-to-peer electronic cash system."⁵ Banks usually know which parties are involved in the transactions, where the transaction is occurring, and have the power to regulate and verify the transaction. Cryptotransactions distinguish themselves from traditional currency transactions by being irreversible, pseudonymous, fast and global, secure and permissionless.⁶

¹ Commodity Futures Trading Com'n v. McDonnell, 287 F.Supp.3d 213, 213 (E.D.N.Y. 2018).

² Satoshi Nakamoto, *Bitcoin v0.1 released*, THE MAIL ARCHIVE (Jan. 09, 2009, 5:05 PM), https://www.mail-archive.com/cryptography@metzdowd.com/msg10142.html. ³ *Id*

⁴ Benjamin Wallace, The Rise and Fall of Bitcoin, WIRED, (Nov. 23, 2011, 02:52 PM),

https://www.wired.com/2011/11/mf-bitcoin/, (last visited, Sep. 20, 2019).

⁵ Brad Mills et al., *What is Cryptocurrency: Everything You Need To Know!*, BLOCKGEEKS, (Sep. 19, 2018), https://blockgeeks.com/guides/what-is-cryptocurrency/.

⁶ Id.

Crypto-transactions are irreversible, which means that essentially "there is no safety net" for crypto-transactions. Once a cryptocurrency transaction is made, there is no way to reverse a fraudulent transaction and the wronged party cannot be compensated for their loss.⁷

Crypto-transactions are pseudonymous, which means that they can be completely anonymous. "Neither transactions nor accounts are connected to real-world identities", only to the cryptocurrency's addresses.⁸ Bitcoin's addresses are "randomly seeming chains of around 30 characters", but there is no way to "connect the real world identity of users with those addresses."⁹ Anyone could be behind the cryptocurrency address, including criminal organizations.

Crypto-transactions are fast and global. "[Crypto]-transactions are propagated nearly instantly" and "can be confirmed in a couple of minutes."¹⁰ Since cryptocurrency transactions have been conducted solely on a global network of computers, there is a complete disregard for the physical location of the people who are conducting the transaction. This characteristic adds to the pseudonymity of cryptocurrency. In fact, the first crypto-transaction mentioned above, the transaction was routed "to a volunteer in England, who then called in a credit card order transatlantically."¹¹ This still occurred in less time than it takes to order a pizza.

Crypto-transactions are secure. Cryptocurrency funds are locked in a "public key cryptocurrency system."¹² Having a public key system means that cryptocurrency transactions can be verified by anyone who has the computer power to do so.¹³ For example, Bitcoin, the most well known and most traded cryptocurrency, uses the SHA 256 Hash algorithm to secure

- ⁸ Id.
- ⁹ Id.

⁷ Id.

¹⁰ Mills et al., *supra* note 5.

¹¹ Benjamin Wallace, *The Rise and Fall of Bitcoin*, WIRED, (Nov. 23, 2011, 02:52 PM), https://www.wired.com/2011/11/mf-bitcoin/.

¹² Mills et al., *supra* note 5.

 $^{^{13}}$ *Id*.

the transactions and ensure that there is no double spending. In order to ensure crypto-transaction security, "miners", a system of computers, solve the encryption and confirm the transactions as they occur. Since only people who have a "private key" can make a transaction and based upon the sheer size and complexity of the algorithm that the miners must solve in order to just confirm a transaction, supposedly a "Bitcoin address is more secure than Fort Knox."¹⁴

Crypto-transactions are permissionless. There is no need to see a teller at a bank or file an application for a loan. As long as you have the funds in your cryptocurrency account, then you are free to make whatever transactions you want. With no need to wait for approval, people can move vast amounts of money in a matter of seconds: "There is no gatekeeper."¹⁵

The combination of all these characteristics created a trading platform that allows for the free trade of goods, but, without regulations, opportunities for abuse and fraud are created. If cryptocurrency gains a stronger enough foothold in the global market, where a significant number of people are using cryptocurrency, then there will be no safety net for those people if they are the victims of fraud or abuse. If cryptocurrency becomes the world's sole currency, then this effect will be global and could be disastrous for the world's economy, like the crash of 1929 was for the United States.

Current Cryptocurrency Use

Although technically not a currency, cryptocurrency can be used for every type of transaction that can be conducted online, which is becoming close to everything. The very features that make cryptocurrency risky also make it attractive to potential investors. Being decentralized means that cryptocurrency value is "not subject to the will of central banks and are only controlled by market dynamics."¹⁶ With the public key and the "mined" verification, there

 $^{^{14}}$ Id.

¹⁵ Id.

¹⁶ Nate Nead, *Cryptocurrency: Growth Trends & Industry Performance*, INVESTMENT BANK (Mar. 6, 2018), https://investmentbank.com/crypto-growth/.

is enough security inherently in place to quell the fears of many critics.¹⁷ Being completely digital means there are "practically no transportation . . . nor transaction costs" that traditional currencies may have.¹⁸ Since cryptocurrency gains its value from its "utility as a medium of exchange," the more people who depend on cryptocurrency to make transactions, the more value cryptocurrency gains.¹⁹

As of February 28, 2018, the current value of the cryptocurrency market was estimated to be \$447.9 billion. The exchange values "soared by 216%."²⁰ Binance, a global cryptocurrency exchange, reported "\$9.5 billion daily trading volume" and "more than 250,000 users on a single day."²¹ Compared to the US market (\$30 trillion in market value and 1-2 billion daily trades) this is still small, but the data showed that the cryptocurrency market is expanding and becoming more integrated into modern financial markets.²²

Some countries, like Japan and Switzerland, have embraced cryptocurrency as a form of currency and created laws favoring initial coin offering ("ICO") for local startups.²³ Some countries, such as Nepal and Bolivia, have rejected the idea and completely banned the use of cryptocurrency.²⁴ Others, like the US and Canada, currently allow the use of cryptocurrency, but are currently formulating how to classify and regulate its use.²⁵ The United States has not made it

https://cryptobriefing.com/top-5-crypto-friendly-nations/.

¹⁷ Id.

¹⁸ Id.

¹⁹ John Kelleher, *Why do Bitcoins have value?*, INVESTOPEDIA, (last updated June 25, 2019), https://www.investopedia.com/ask/answers/100314/why-do-bitcoins-have-value.asp.

²⁰ Nead, *supra* note 16.

²¹ Gareth Jenkinson, *Moment of Truth for EOS: What's Next for \$4 bln EOSIO Following Launch of v1.0*, COINTELEGRAPH, (June 5, 2018), https://cointelegraph.com/news/moment-of-truth-for-eos-whats-next-for-4-bln-eosio-following-launch-of-v10.

²² Vito J. Racanelli, *The U.S. Stock Market Is Now Worth \$30 Trillion*, BARRON'S (Jan. 18, 2018, 9:28 AM), https://www.barrons.com/articles/the-u-s-stock-market-is-now-worth-30-trillion-1516285704.

²³ Sam Town, *The Top 5 Crypto-Friendly Nations*, CRYPTO BRIEFING (Feb. 17, 2018),

²⁴ Massimo Di Giuda, *Countries where the cryptocurrencies are banned: busted for Bitcoin*, BITNEWS TODAY (April 25, 2018), https://bitnewstoday.com/market/bitcoin/countries-where-the-cryptocurrencies-are-banned-busted-for-bitcoin/.

²⁵ Vivek Sancheti, *List of Coutnries where Bitcoin is Legal* (Feb. 24, 2018), https://www.cryptoground.com/a/list-of-countries-where-bitcoin-is-legal

known whether it approves of cryptocurrency in financial transaction, however it has not overtly banned the use of cryptocurrency.

Cryptocurrency Problems

Even though part of the world has accepted cryptocurrency, there are major concerns about its legal use. The features of cryptocurrency listed above make it particularly susceptible to financial crimes, including money laundering, tax evasion, and purchase of illegal items or services. According to a study conducted in early 2018, an estimated \$76 billion of illegal activity was conducted using crypto-transactions, which is roughly "the scale of the US and European markets for illegal drugs."²⁶ The cryptocurrency market has been established to provide an alternative to fiat money, but criminal activity has also latched on. Besides cryptocurrencies' own internal mechanisms, there is no policing authority to punish those who abuse the cryptocurrency system.

Cryptocurrency Regulations

Congress has yet to issue any official legislation regarding cryptocurrencies, but it did speak about the cryptocurrency market and possible regulation in the 2018 Joint Economic Report ("Report").²⁷ The Joint Economic Committee, who penned the Report, stated that future regulations "will require unique solutions that balance the needs of consumer protection, security, and entrepreneurship."²⁸ Currently, because cryptocurrency is classified as either a "commodity, security, currency, [or] property," Congress has urged "regulatory agencies […] to coordinate to ensure they do not work at cross purposes" so that cryptocurrencies are effectively regulated.²⁹

²⁶ Sean Foley, *Sex, Drugs, and Bitcoin: How Much Illegal Activity is Financed Through Cryptocurrencies?*, REVIEW OF FINANCIAL STUDIES, FORTHCOMING, Jan. 2018, at 1.

²⁷ H.R. REP. No. 115-596 at 225 (2018).

²⁸ Id.

²⁹ *Id.* at 224.

The court in *Commodity Futures Trading Comm'n v. McDonnell* outlined nine possible scenarios for cryptocurrency regulation:

i. No regulation;

ii. Partial regulation through criminal prosecutions of Ponzi-like schemes by the

Department of Justice ("DOJ");

iii. Regulation by the Commodity Futures Trading Commission ("CFTC");

iv. Regulation by the Securities and Exchange Commission ("SEC");

v. Regulation by the Treasury Department's Financial Enforcement Network ("FinCEN");

vi. Regulation by the Internal Revenue Service ("IRS");

vii. Regulation by private exchanges;

viii. Regulation by individual states;

ix. A combination of any of the above.³⁰

Although these are possible methods of regulation, they are all not immediately viable. First, the propensity for illegal activity to occur using cryptocurrency means that regulation is possible. There needs to be some form of regulation or a regulatory body to curb the illegal activity and to secure the safe use for future investors. Therefore, option (i) will not be considered. Second, because cryptocurrency is relatively new it is also relatively undefined. This means that whatever regulatory body wants to monitor cryptocurrency will need to make sure that cryptocurrency falls within the definition of whatever they regulate. Third, there is another option: the creation of a new agency either within an existing regulatory body or on its own. This would occur only if none of the other regulatory bodies mentioned above are able to justify their own regulation, but it is worth considering.

³⁰ Commodity Futures Trading Comm'n v. McDonnell, 287 F. Supp. 3d 213, 220-22 (N.Y. 2018).

I. Regulation by the DOJ

The DOJ was established in 1870 by the Act to Establish the Department of Justice to be "an executive department of the government of the United States of which the Attorney General shall be its head.³¹ The Attorney General has the authority to control the Department of Justice and represents "the United States in legal matters generally."³² The DOJ's mission statement outlines their goals and as an agency will "enforce the law and defend the interests of the United States according to the law; [...] ensure public safety against threats foreign and domestic; [...] provide federal leadership in preventing and controlling crime; [...] seek just punishment for those guilty of unlawful behavior; and to ensure fair and impartial administration of justice for all Americans."³³ It is clear that the DOJ only has authority over people who have committed crimes and their punishment.

CFTC v. McDonnell suggested that the DOJ would exercise its jurisdiction over cryptocurrency crimes if they are a Ponzi-like scheme.³⁴ A Ponzi scheme is a type of "investment fraud that involves the payment of purported returns to existing investors from funds contributed by new investors."³⁵ One of the most famous examples of a Ponzi scheme includes Bernard Madoff, who defrauded investors of about \$36 billion dollars and is currently serving a 150-year sentence as a result.³⁶

Being so limited in its regulatory ability, the DOJ would only be able to regulate cryptocurrency crimes if they are part of a Ponzi-like scheme. Cryptocurrency's characteristic of pseudonymity would prevent investors from identifying who they're investing with, unless the

³¹ Act to establish the Department of Justice, ch.150, 16 Stat. 162 (1870).

³² 28 C.F.R. §0.5(b) (2016).

³³ About DOJ, U.S. DEP'T OF JUSTICE, https://www.justice.gov/about (last visited Sept. 20, 2019).

³⁴ Commodity Futures Trading Comm'n v. McDonnell, 287 F. Supp.3d 213, 220-22 (E.D.N.Y. 2018).

³⁵ *Ponzi Schemes*, U.S. SEC. & EXCH. COMM'N, (Oct. 9, 2013), https://www.sec.gov/fast-answers/answersponzihtm.html.

³⁶ *The Madoff Scam: Meet the Liquidator*, CBS NEWS, (Sept. 25, 2009), https://www.cbsnews.com/news/the-madoff-scam-meet-the-liquidator-25-09-2009/.

investors knew the identity of perpetrator of the Ponzi scheme in the real world. Further, there are many other crimes that involve cryptocurrency, such as legitimate purchases for illicit substances. These would not be under the jurisdiction suggested by *CFTC v. McDonnell* and would severely limit the regulatory power of the DOJ.

II. Regulation by the CFTC

The CFTC was formed in 1974 and granted power under the Commodities Exchange Act of 1936 ("CEA") in order to "foster open, transparent, competitive, and financially sound markets . . . to avoid systemic risk, . . . to protect market users and their funds, consumers, and the public from fraud, manipulation, and abusive practices related to derivatives and other products that are subject to the CEA."³⁷ The CEA definition for "commodity" is very broad and includes many items. Traditionally, the CFTC has overseen the "commodity futures markets" that the Department of Agriculture once oversaw such as wheat, corn, and cotton.³⁸ These commodity futures markets, now known as "designated contract markets" ("DCMs"), have been expanded to include energy and metals commodities and financial products, such as "interest rates, stock indexes, and foreign currency."³⁹ After the financial crisis of 2008, the CFTC was given expanded powers under the Dodd-Frank Act to enhance the CFTC's "rulemaking and enforcement authorities with respect to, among others, all registered entities and intermediaries subject to the [CFTC's] oversight."⁴⁰ Because of the broad definition of the term "commodity" a commodity means: goods and articles (such as wheat or corn), "motion picture box office

³⁷ *Mission & Responsibilities*, U.S. Commodity Futures Trading Comm'n, (last updated 2018), https://www.cftc.gov/About/MissionResponsibilities/index.htm.

³⁸ Id.

³⁹ Id.

⁴⁰ *History of the CFTC*: CFTC History in the 2010s, U.S. COMMODITY FUTURES TRADING COMM'N, https://www.cftc.gov/About/HistoryoftheCFTC/history_2010s.html (last visited Sept. 20, 2019).

receipts (or any index, measure, value or date related to such receipts)," and "all services, rights and interests . . . in which contracts for future delivery [that] presently or in the future dealt in."⁴¹

The CFTC has jurisdiction over "futures, options, and derivatives contracts."⁴² A derivative is a financial contract that "derives its value from an underlying asset."⁴³ A derivative contract binds the price of the derivative once the contract for the sale or purchase of the derivative has been made.⁴⁴ For cryptocurrency, the price is bound once the cryptocurrency becomes part of a blockchain and is verified by a cryptocurrency miner.⁴⁵ Because cryptocurrency derives its value from the number of participants in the crypto-economy and the price of cryptocurrency becomes fixed upon entering and being verified by a blockchain, cryptocurrency acts as a derivative contract. And because cryptocurrency acts as a derivative contract, it falls within the jurisdiction of the CFTC.

In *Coinflip, Inc.*, the CFTC held this reasoning and stated that "bitcoin and other [cryptocurrencies] are encompassed in the definition and properly defined as commodities."⁴⁶ The CFTC's jurisdiction over cryptocurrencies was upheld in *CFTC v. McDonnell*.⁴⁷ The court in *CFTC* held that cryptocurrencies "are 'goods' exchanged in a market for a uniform quality and value" and "[t]hey fall well within the common definition of 'commodity' as well as the CEA's definition of 'commodities."⁴⁸ The *McDonnell* court based some of its reasoning off of the fact that the CFTC had previously been allowed to issue a judgement on the misuse of

⁴¹ 7 U.S.C. Sec. 1a(9) (2019).

⁴² LabCFTC, *A CFTC Primer on Virtual Currencies*, U.S. COMMODITY FUTURES TRADING COMMISSION 11 (Oct. 17, 2017),

 $https://www.cftc.gov/sites/default/files/idc/groups/public/\%40 customer protection/documents/file/labcftc_primer currencies 100417.pdf.$

⁴³ Kimberly Amadeo, *Derivatives, With Their Risks and Rewards*, BALANCE, https://www.thebalance.com/what-arederivatives-3305833 (last updated Feb. 12, 2019).

⁴⁴ Id.

⁴⁵ Id.

⁴⁶ Coinflip, Inc., CFTC No. 15-29, (Sept. 17, 2015).

⁴⁷ McDonnell, *supra* note 34.

⁴⁸ *Id.* at 228.

cryptocurrency in *Coinflip, Inc.*, but that is a minor part of the reasoning.⁴⁹ The court mainly focuses on the definition provided by the CEA and the common definition of commodity.⁵⁰

At this time, no other cases have been brought forth to further define the CFTC's jurisdiction in the matters of cryptocurrencies, nor has the CFTC released any further statements regarding the regulation of cryptocurrencies. Much like the SEC, the CFTC released a statement stating that it would more than likely not seek to further regulate the cryptocurrency market just because of the unknown nature of cryptocurrency themselves.⁴² In 2015, Commissioner Mark Wetjen implied that the CFTC "may be [a] simply interested observer of the bitcoin market" until the status changes.⁵¹

Current CFTC regulation has been slightly effective in stopping further actions of people who are abusing or manipulating the cryptocurrency market after the abuse or manipulation has taken place. Since the CFTC has not taken any action to regulate cryptocurrency market activity, this the best that they can do and until the CFTC is given direct authority or is able to directly observe the market, there can be no further regulation of cryptocurrency by the CFTC. Until the CFTC is able to monitor and regulate cryptocurrency transactions in real time, the current regulations will be incomplete.

III. Regulation by the SEC

According to the SEC, their mission is to "protect investors, maintain fair, orderly, and efficient markets, and facilitate capital formation."⁵² The SEC gained its power from the Securities Act of 1933 ("Securities Act") and the Security Exchange Act of 1934 ("Exchange

⁴⁹ *Id.* at 222.

⁵⁰ Id. at 225.

⁵¹ Pete Rizzo, *CFTC Commissioner: Market Manipulation Could Shape Bitcoin's Future*, COINDESK (updated Jan. 9, 2015, 10:47 AM), https://www.coindesk.com/cftc-commissioner-mark-wetjen-bitcoin/.

⁵² What We Do, U.S. SEC. & EXCH. COMM'N, https://www.sec.gov/Article/whatwedo.html, (last modified June 10, 2013).

Act"). The objectives of the Securities Act are to "require that investors receive financial and other significant information concerning securities being offered for public safety and prohibit deceit, misrepresentations, and other fraud in the sale of securities." *Id.* The Securities Act governs all security trading within the US. The Securities Act defined a "security" to be:

"any note, stock, treasury stock, security future, security-based swap, bond, debenture, evidence of indebtedness, certificate of interest or participation in any profit-sharing agreement, collateral-trust certificate, preorganization certificate or subscription, transferable share, investment contract, voting-trust certificate, certificate of deposit for a security, fractional undivided interest in oil, gas, or other mineral rights, any put, call, straddle, option, or privilege on any security, certificate of deposit, or group or index of securities (including any interest therein or based on the value thereof), or any put, call, straddle, option, or privilege entered into on a national securities exchange relating to foreign currency, or, in general, any interest or instrument commonly known as a "security", or any certificate of interest or participation in, temporary or interim certificate for, receipt for, guarantee of, or warrant or right to subscribe to or purchase, any of the foregoing."⁵³

The Exchange Act empowered the SEC to "register, regulate, and oversee brokerage

firms, transfer agents, and clearing agencies as well as the nation's securities self-regulatory organizations."⁵⁴ The SEC normally conduct an investigation of a financial institution there are signs of financial crimes such as fraud, misrepresentation, insider trading or other violations. Once the SEC finds a violation, the matter is usually resolved by civil action or administrative action, but in many cases the institution charged with the violation will settle the matter without a trial, in the form of a fine.

The SEC been given expanded regulatory power in recent years because of the passing of the Sarbanes-Oxley Act of 2002 ("Oxley Act") and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd Act"). The Oxley Act and the Dodd Act were enacted

⁵³ Securities Act of 1933, 15 U.S.C. § 77b(a)(1) (1933).

⁵⁴ U.S. SEC. & EXCH. COMM'N, *supra* note 45.

so the SEC could better monitor and police potential financial crimes that involve significant collaboration and fraud that would negatively affect investor trust and harm the market.

As far as cryptocurrency is concerned, the SEC released a statement in December of 2017 ("the Statement") in which the SEC "committed to promoting capital formation" but warned investors of the normal precautions of investing in unknown financial items, such as making sure investors conduct their due diligence before investing.⁵⁵ According to the Statement, the SEC currently emphasizes two points about cryptocurrencies: First, although cryptocurrencies are not yet labeled as securities, "promoters must either (1) be able to demonstrate that the currency or product is not a security or (2) comply with applicable registration and other requirements under our securities laws." Second, brokers of cryptocurrencies are recommended to "exercise particular caution, including ensuring that their cryptocurrency activities are not undermining their anti-money laundering and know-your-customer obligations."⁵⁶ Generally, brokers should treat cryptocurrencies as "cash being handed from one party to [another]."⁵⁷ The SEC has labelled initial coin offerings ("ICOs") as securities.⁵⁸ ICOs are offered to investors "on the potential for [cryptocurrency] to increase in value" or "otherwise profit from the [cryptocurrency]."⁵⁹ These are characteristics that align with the definition of a 'security' in that ICOs are "certificates of interest or participation" which include "any interest therein or based on the value."⁶⁰ The SEC confirmed that because of the security-like nature of ICOs, ICOs "directly implicate the securities registration requirements and other investor protection provisions of...federal securities law."61

⁵⁹ Id.

⁵⁵ Jay Clayton, *Statement on Cryptocurrencies and Initial Coin Offerings*, U.S. SEC. & EXCH. COMM'N (Dec. 11, 2017), https://www.sec.gov/news/public-statement/statement-clayton-2017-12-11.

⁵⁶ Id.

⁵⁷ Id.

⁵⁸ Id.

⁶⁰ Securities Act of 1933, 15 U.S.C. § 77b(a)(1) (1933).

⁶¹ Jay Clayton, *Statement on Cryptocurrenices and Initial Coin Offerings*, U.S. SECURITIES & EXCHANGE COMMISSION (Dec. 11, 2017), https://www.sec.gov/news/public-statement/statement-clayton-2017-12-11.

Other than this statement, the SEC has released no further information as whether they are issuing regulations specifically aimed at cryptocurrencies beyond ICOs. But the SEC will "continue to police [cryptocurrency] vigorously."⁶²

IV. Regulation by the FinCEN

FinCEN was established in April 1990 by Treasury Order Number 105-08.⁶³ FinCEN's current mission is to "safeguard the financial system from illicit use, combat money laundering, and promote national security through the strategic use of financial authorities and the collection, analysis, and dissemination of financial intelligence."⁶⁴

On March 13, 2013, FinCEN released memo FIN-2013-G001 ("FIN-2013-G001") entitled "Application of FinCEN's Regulations to Persons Administering, Exchanging, or Using Virtual Currencies".⁶⁵ In FIN-2013-G001, FinCEN asserted its jurisdiction over cryptocurrencies through the Bank Secrecy Act, which was created to ensure the proper use of money service businesses ("MSBs").⁶⁶ MSBs are businesses that are "dealers in foreign exchange, check cashiers, providers of prepaid access, money transmitters, [the] U.S. Postal Service [or a] provider of prepaid access."⁶⁷ FinCEN asserted its jurisdiction over cryptocurrencies by stating that, although cryptocurrency itself is not an MSB, "an administrator or exchanger is an MSB under FinCEN's regulations, specifically, a money transmitter".⁶⁸ FinCEN has the authority to enforce sanctions against criminal punishments, but FinCEN does not have the authority to regulate or monitor the market.

⁶² Id.

⁶³ Financial Crimes Enforcement Network, U.S. DEPARTMENT OF THE TREASURY,

https://www.treasury.gov/about/history/Pages/fincen.aspx.

⁶⁴ *Mission*, FINANCIAL CRIMES ENFORCEMENT NETWORK, https://www.fincen.gov/about/mission (last visited Sept. 20, 2019).

 ⁶⁵ Department of the Treasury, *FIN-2013-G00, Application of FinCEN's Regulations to Persons Administering, Exchanging, or Using Virtual Currencies*, FINANCIAL CRIMES ENFORCEMENT NETWORK, (last visited February 20, 2020. https://www.fincen.gov/sites/default/files/shared/FIN-2013-G001.pdf
⁶⁶ Id.

⁶⁷ 31 C.F.R. § 1010.100(ff)(1)-(6).

⁶⁸ U.S. DEP'T OF THE TREASURY, *supra* note 56.

Because of its limited role, FinCEN cannot effectively regulate the emerging cryptocurrency market. FinCEN can only police possible illicit activity but cannot prevent it.

V. Regulation by the IRS

The Internal Revenue Service ("IRS") was founded in 1913 with the ratification of the 16th Amendment, which granted Congress the "authority to enact an income tax."⁶⁹ Currently, the IRS's mission is to "[p]rovide America's taxpayers top quality service by helping them understand and meet their tax responsibilities and by enforc[ing] the tax law with integrity and fairness to all."⁷⁰

The IRS issued Notice 2014-21 ("Notice"), which was a general FAQ for the use and taxation of cryptocurrency. The Notice stated, "[cryptocurrency] is treated as property [and] [g]eneral tax principles applicable to property transactions apply to transactions using [cryptocurrency]."⁷¹ This means that the IRS has the ability to enforce tax laws on "wages paid to employees [and] payments using [cryptocurrency] made to independent contractors"⁷² But, the IRS has not released another statement broadening the scope of its regulatory powers for cryptocurrency since the Notice. Therefore, cryptocurrency will only come under the jurisdiction of the IRS if the cryptocurrency has previously been used to avoid paying taxes or other violations of the tax code.

The IRS tasked its Criminal Investigation Division to investigate and research how cryptocurrency can be used to enable tax evasion. In 2015, the Criminal Investigation Division

⁶⁹ IRS History Timeline (last modified Mar. 12, 2019), https://www.irs.gov/irs-history-timeline.

⁷⁰ The Agency, Its Mission and Statutory Authority: The IRS Mission, IRS, https://www.irs.gov/about-irs/the-agencyits-mission-and-statutory-authority (last updated Aug. 9, 2019).

⁷¹ Notice 2014-21 (Mar. 25, 2014), https://www.irs.gov/irb/2014-16_IRB#NOT-2014-21.

⁷² IRS Virtual Currency Guidance: Virtual Currency Is Treated as Property for U.S. Federal Tax Purposes; General Rules for Property Transactions Apply (Mar. 25, 2014), https://www.irs.gov/newsroom/irs-virtual-currency-guidance.

filed a legal summons for Coinbase, a cryptocurrency exchange, to turn over the names of its accounts from 2013 to 2015, many of which were suspected of tax evasion.⁷³

The IRS tasked its Criminal Investigation Division to investigate and research how cryptocurrency can be used to enable tax evasion. In 2015, the Criminal Investigation Division filed legal summons for a cryptocurrency exchange, Coinbase, to turn over the names of its accounts from 2013 to 2015, many of which were suspected of tax evasion.⁷⁴ On November 29, a judge held that the summons must be upheld and ordered Coinbase to "turn over information on accounts with at least \$20,000."⁷⁵

The IRS has not released any additional information about whether they are seeking to expand their scope of jurisdiction over cryptocurrency. It appears as if the IRS will continue to research the cryptocurrency market through its Criminal Investigation Division and order summons for exchanges that may appears to enable violations of the tax code. The IRS is relegated to just violations of the tax code, to their jurisdiction is quite limited.

VI. Regulation by the Private Exchanges

Cryptocurrency exchanges, such as Binance and Bittrex, have existed as long as the cryptocurrency market has been established. They are a necessity to facilitating the trading and verification of cryptocurrency. Unlike traditional exchanges, cryptocurrency exchanges need not be a physical location, rather most are just "websites where [someone] can buy, sell or exchange cryptocurrencies for . . . digital . . . or traditional currency."⁷⁶

⁷³ David Voreacos, *IRS Cops Are Scouring Crypto Accounts to Build Tax Evasion Cases* (Feb. 8, 2018), https://www.bloomberg.com/news/articles/2018-02-08/irs-cops-scouring-crypto-accounts-to-build-tax-evasion-cases.

⁷⁴ Id. ⁷⁵ Id.

⁷⁶ Ameer Rosic, *The Best Cryptocurrency Exchanges: Most Comprehensive Guide List*, BLOCKGEEKS (2017), https://blockgeeks.com/guides/best-cryptocurrency-exchanges/ (last visited Sept. 19, 2019).

Since cryptocurrencies exist as a decentralized system of currency, they maintain their use largely through reputation. Cryptocurrency exchanges that have been hacked, such as the Mt. Gox hack in 2014 that resulted in \$473 millions worth of cryptocurrency being stolen or "around 7% of the world's supply of [cryptocurrency]" at the time, have led to a lack of faith in the cryptocurrency market and the closing of the exchange.⁷⁷

It would be in the best interest of cryptocurrency exchanges to self-regulate since if investors feel confident in the safety and reliability of cryptocurrency exchanges. The continued safe use of cryptocurrency would promote investor confidence. Japan, a leader in the use of cryptocurrency, has had two organizations of exchange markets form: the Japan Blockchain Association ("JBA") and the Japan Cryptocurrency Business Association ("JCBA").⁷⁸ The opinion of whether cryptocurrency exchanges should be self-regulating is "divided."⁷⁹ The JBA would consider taking a regulatory role "if it were necessary for the 'healthy development' of blockchain" and the JCBA stated that "the authorities also feel the need for an approved selfregulation body."⁸⁰ The leading cryptocurrency regulator in Japan, the Financial Service Agency ("FSA"), has voiced a similar opinion that "creating voluntary rules is critical from a user protection perspective."⁸¹ Despite the formation of these organizations, it seems that little has been done in the way of actual regulation by the JBA or JCBA, despite Tokyo based cryptocurrency exchange Coincheck Inc. being hacked for "nearly \$500 million in digital tokens."⁸²

⁷⁷ Ameer Rosic, 5 High Profile Cryptocurrency Hacks, BLOCKGEEKS (2018),

https://blockgeeks.com/guides/cryptocurrency-hacks/ (last visited Feb. 21, 2020).

⁷⁸ Japan Tries Light Touch in Bringing Cryptocurrencies out of Regulatory Limbo, NIKKEI ASIAN REVIEW (Sept 30, 2017), https://asia.nikkei.com/Business/Banking-Finance/Japan-tries-light-touch-in-bringing-cryptocurrencies-out-of-regulatory-limbo.

⁷⁹ Id.

⁸⁰ *Id*.

⁸¹ *Id*.

⁸² How to Steal \$500 Million in Cryptocurrency, BLOOMBERG (Jan. 31, 2018),

http://fortune.com/2018/01/31/coincheck-hack-how/.

In the United Kingdom, several cryptocurrency companies have formed CryptoUK in an attempt to "self-regulate" the cryptocurrency market.⁸³ CryptoUK has yet to make any regulatory decisions, but the hopes are that the "self-regulatory body is expected to advocate for interests of the cryptocurrency industry and create awareness on how the sector operates."⁸⁴ CryptoUK will regulate "cryptocurrency exchange and trading platforms" and will represent investors through "a productive code of conduct or code of ethics."⁸⁵ This "code of ethics" is said to include sections on "industry standards, proactive disclosure of information relating to pricing, fees and risks, and appropriate checks to ascertain investor suitability."⁸⁶ It has yet to be seen if the "code of ethics" have been effective.

VII. Regulation by Individual States

Individual states have already begun to issue their own legislation concerning cryptocurrency. Some states, like New York and California, have issued comprehensive bills dictating the nature and regulation of cryptocurrency.⁸⁷ Some have legislation pending, but many have yet to address the cryptocurrency market. The types of legislation are unique to each state, but follow some of the same formatting.

New York has started to develop "Bit Licenses" for people who wish to trade in cryptocurrency. The regulation states that "no person shall, without a license obtained from the superintendent . . . , engage in any virtual currency business activity."⁸⁸ The Bit License required that a registered licensee "comply with all applicable federal and state laws, rules, and regulations," appoint a compliance officer, and "maintain and enforce written compliance

 ⁸³ David Drake, Why Self-Regulation Makes Sense to Cryptocurrency Market Player, EQUITIES.COM (Mar. 2, 2018), https://www.equities.com/news/why-self-regulation-makes-sense-to-cryptocurrency-market-players.
⁸⁴ Id.

⁸⁵ *Id*.

⁸⁶ Id

⁸⁷ N.Y. Comp. Codes R. & Regs. tit 23 (2015).

⁸⁸ *Id.* at 200.3(a).

policies."⁸⁹ Effectively, to be able to trade, invest or use cryptocurrency in a financial setting, New York makes the crypto-financier effectively display that it is in line with all regulations that current currencies and other financial securities are.

Recently, Arizona introduced Senate Bill 1091 ("1091"), which contained a provision that allowed residents to pay taxes in "a payment gateway, such as Bitcoin or other cryptocurrency, using electronic peer-to-peer systems."⁹⁰ The bill passed was vetoed on May 16, 2018 and there has been no further news of cryptocurrency being used or regulated by Arizona.

Washington, despite a thriving tech scene, passed a bill " that requires cryptocurrency exchanges to maintain cash reserves equivalent to the transacted volume."⁹¹ This legislation has been seen as "openly hostile" to the cryptocurrency market because it requires traders to essentially care twice the amount of capital to place trades, doubling expenses and driving the cryptocurrency market from the state.⁹²

Currently, nine states have cryptocurrency regulations in place, while seven more have pending regulations.⁹³ The other thirty-five states have no regulations in place. The nine states that have regulations in place are the states with the biggest economies or where significant financial habits take place, such as trading or incorporations. It would make sense that these states are the first to take a stance on cryptocurrency. Other states are few in providing regulations for cryptocurrency, even ones that requires cryptocurrency traders to follow federal regulations. But this may be because, despite a growing cryptocurrency market, the states do not see the necessity to regulate it or they have other priorities to attend to first.

VIII. Regulation by a New Agency

⁸⁹ *Id.* at 200.7(b)-(c).

⁹⁰ S.B. 1091 § 43-505(2), 53d Leg., 2d Reg. Sess. (Ariz. 2018).

⁹¹ Rakesh Sharma, *More US States May Roll Out Cryptocurrency Regulations*, INVESTOPEDIA (June 25, 2019), https://www.investopedia.com/news/majority-us-states-are-still-acknowledge-cryptocurrencies/.

 $^{^{92}}$ *Id*

Just as the SEC was created by the Securities Act and the Exchange Act and the CFTC was created by the CEA, it would be possible for new legislation to create an agency that would be responsible for regulation of cryptocurrency. This would relieve the pressure of current agencies such as the SEC and CFTC who are attempting to frame cryptocurrencies within their jurisdictions as securities and commodities respectively.

This legislation itself would need to be approved by Congress, which could take years and is not guaranteed to work. It would make more sense for legislation to approve a new agency as part of a current regulatory body.

Effectiveness of Current Regulations

There have been successes in making sure there aren't abuses of cryptocurrency, as exampled by *Coinflip* and *CFTC v. McDonnell*, but there are still plenty of undocumented and unreported crimes happening because of cryptocurrency's unique nature. Besides the constant threat of exchanges and wallets being hacked, as in Mt. Gox hack, the threat of cryptocurrency being used to support illicit activity is an inherent problem for a currency that is purposefully anonymous, instantaneous and decentralized. The perfect example is "Silk Road", a "large-scale 'darknet' market" that, from 2011-2013, was used to buy and sell "over \$200 million in drugs and illegal goods, ranging from weapons to forged driver's licenses "⁹⁴ Silk Road was shut down in October 2013, but a replacement, Silk Road 2.0, "appeared the next month and remained active for about a year before authorities shut it down."⁹⁵ After Silk Road 2.0 was shut down, another darknet market, AlphaBay, replaced it and from "2015 to 2017, transactions totaled more than \$1 billion in bitcoin and other digital currencies."⁹⁶ Cryptocurrency inherently draws criminal activity because of its setup. Even though authorities are becoming better at

⁹⁴ Corinne Ramey, *The Crypto Crime Wave Is Here*, WSJ (Apr. 26, 2018), https://www.wsj.com/articles/the-crypto-crime-wave-is-here-1524753366.

⁹⁵ Id.

⁹⁶ Id.

stopping the activity through experience, without regulations, these types of sites will continue to be operated and criminal activity will always be characteristic of cryptocurrency. The current regulations from the SEC, CFTC, IRS, FinCEN, and individual states are incomplete because they only consider cryptocurrency in a certain fashion. CFTC has jurisdiction when cryptocurrency is a commodity, SEC has jurisdiction when cryptocurrency is a security, IRS when it is used to pay taxes, FinCEN when criminal activity have already come to light, and the individual states whenever they feel like making their laws. The regulation and reporting aspect is arbitrary at best and does not amount to the type of coverage necessary needed to validate cryptocurrency as a viable tradeable item regardless of its rising popularity and use.

Future Regulations

It is clear that the cryptocurrency market cannot go on without some form of regulation. Cryptocurrency is too readily available for illicit activity, and being a decentralized currency may relieve it from traditional taxes and fees, but without regulation, it is highly likely that investor confidence will drop and the currency will disappear on its own. Although early investors are confident that cryptocurrency is the currency of the future, public interest tells a different story. When Bitcoin's price dropped from \$20,000 to roughly \$3,2000 per coin, wiping out nearly fifty-one percent of its value, public interest via Google searches similarly rose and fell. ⁹⁷ Further, government regulations have also hindered investment as cryptocurrency's decentralized nature is incrementally becoming centralized. *CFTC v. McDonnell* listed several ways to possibly regulate the cryptocurrency market, each discussed above.⁹⁸

Leaving cryptocurrency markets to regulate themselves cannot continue with the past and potential financial crimes. However, current regulation by the current agencies is also incomplete

⁹⁷ Nicolas Ortega, *Bitcoin Reached An All-Time High Last Year. Now, You Might Be Digging For Coal*, NBCNEWS.COM (Dec. 19, 2018), https://www.nbcnews.com/business/markets/bitcoin-high-2017-decline-2018-data-n949576.

⁹⁸ McDonnell, *supra* note 34.

and somewhat ineffective. Since cryptocurrency crime is usually only caught once the criminal attempts to convert cryptocurrency to government-backed currency, regulation of cryptocurrency will need to be more complete to accommodate tracking crypto-transactions as well as it is converted.

For cryptocurrency regulation, several things need to happen. First, cryptocurrency needs to be properly defined in legal terms. This would help determine which regulatory body would have jurisdiction, if any. Second, statutes need to be amended to determined the procedure for reporting and tracking cryptocurrency use to meet the standards that are held to other financial institutions. Third, since cryptocurrency is basically a different kind of currency rather than a financial method, the statutes will need to be comprehensive, covering all the possible uses for cryptocurrency, which is pretty much anything.

Eliminating the options of no regulation and regulation by the private exchanges themselves, for the reasons listed above, we can look to the other options from *CFTC v*. *McDonnell*.⁹⁹ Each of the regulatory bodies currently in place, the DOJ, CFTC, SEC, FinCEN, IRS, all have their drawbacks. Each are limited to their own jurisdictions, which alone do not completely cover cryptocurrency. Each regulatory body would have to relinquish some of their regulatory power or work effectively together to properly ensure regulation. The idea of the all the regulatory bodies relinquishing their power or cooperating in an effective manner is somewhat outlandish. Cryptocurrency is too unique for a joint force, rather it requires a dedicated task force alone.

Each state could pass legislation that would allow such a task force to exist. Unfortunately, there are fifty states and the problem of cooperation arises again. As stated above, each state is free to regulate cryptocurrencies as they wish so there is no guarantee that each state

⁹⁹ McDonnell, *supra* note 34.

would pass legislation that would be uniform with every other state's legislation. Since cryptocurrency is a fast and global system that works instantaneously, there needs to be uniformity in the legislation. Although states are encouraged to regulate cryptocurrency on their own, there needs to a baseline of regulation that is applicable to the entire United States. That is why the regulatory body needs to be federal.

The best option would be for Congress to evaluate cryptocurrency and create legislation that would properly regulate the market. First, new legislation would properly define what cryptocurrency is legally. Second, the legislation would create the procedure for reporting and monitoring crypto-transactions and the entire use of the crypto-market within the United States. Third, the legislation would create a separate and independent agency to oversee the cryptocurrency market as crypto-transactions happens and to punish those who abuse the system. This is the most necessary step because the definitions used to provide context to legislation to what the regulatory bodies regulate. This is shown by definitions given with each regulatory body's analysis. Absent the ability to create a new agency through legislation, Congress could properly define what cryptocurrency is and therefore which regulatory body is responsible for the monitoring of the crypto-market. Otherwise, it is likely that cryptocurrency will continue to be used illicit activity and the confidence in cryptocurrency will continue to drop. At some point, the lack of confidence will cause the collapse of cryptocurrency. For potential cryptocurrencies and their investors, the choice is either to regulate or die.

Nano-Fed Americans: Novel & Untested Food Additives Are Bypassing the Regulatory System into Consumers Mouths

Alison T. Burrows

Abstract

Nanotechnology is promised to revolutionize the agricultural-food industry. But Americans are unknowingly consuming nanofoods at their own risk under the assumption that the Food and Drug Administration ("FDA") ensures the safety of all novel substances added to food. But a broken regulatory framework has permitted the food industry to bypass FDA approval and market untested lab-created food products. This note first summarizes the history of novel food additives in the United States and provides insight into the structure and incentives behind the Food Additives Amendments ("FAA") and "generally recognized as safe" ("GRAS") exception. Next follows a brief introduction to nanotechnology, applications in the food industry, and potential health and safety concerns. The final section argues that, despite inherent definitional challenges, current legal authority is equipped to regulate nanomaterials in food if it were not for the GRAS exception permitting untested nanofoods to enter the market.

Introduction

The modern food industry is driven by consumers continuous quest for a sustained supply of safe, nutritious, diverse, affordable, and enjoyable food.¹⁰⁰ Long gone is the whole food diet of our ancestors. Today, food has transformed into a processed and packaged diet developed to satisfy modern consumer demand for flavorful, safe, nutritious, convenient, and affordable food.¹⁰¹

Technological innovation has engineered foods laden with unfamiliar ingredients. Additives are designed to hit the "bliss point" of flavor and texture and manipulated to eliminate undesirable nutrients like fat, sugar, and gluten, only to be replaced with synthetic substitutes.¹⁰² With so many unfamiliar ingredients on modern food labels, many consumers are concerned about their long-term safety.

American consumers assume the Food and Drug Administration ("FDA") oversees the safety of these additives since Congress passed legislation that requires the agency to ensure the safety of food additives before marketing to consumers. In reality, the FDA exercises shockingly little oversight of novel food additives, relying instead on food producers and manufacturers to conduct their own safety tests and determinations. Additionally, the FDA has almost no knowledge of what type of substances industries add to foods; and consequently, the FDA has no means to study and evaluate potentially harmful effects. In light of rapidly emerging

¹⁰⁰ Qasim Chaudhry, et al., Nanoscience & Nanotechnology Series: Nanotechnologies in Food 5 (Qasim Chaudhry, Laurence Castle & Richard Watkins eds., The Royal Soc'y of Chemistry 2017)(2010).

¹⁰¹ Overview of Food Ingredients, Additives & Colors, U.S. FOOD & DRUG ADMIN. WITH INT'L FOOD INFO. COUNCIL, FOOD INGREDIENTS, ADDITIVES & COLORS, https://www.fda.gov/food/food-ingredientspackaging/overview-food-ingredients-additives-colors (last updated Feb. 6, 2018).

¹⁰² SEE MICHAEL MOSS, SALT, SUGAR, FAT: HOW THE FOOD GIANTS HOOKED US, at xix, 20, 71 (2013)

nanotechnology poised to revolutionize the food industry, it is imperative the FDA prioritize consumer safety.

I. A History of Novel Food Regulation in the United States

The FDA "protects public health by assuring... the safety and security of our nation's food supply." Starting in the late 1800s, technological innovation began to threaten consumer health with the introduction of industrially produced, packaged, and processed foods that contained unknown contaminants and additives. Since then, the FDA has implemented and reconstructed regulation designed to ensure consumer safety.

A. The Pure Foods and Drugs Act of 1906

In 1902, the chief chemist in the U.S. Department of Agriculture, Harvey Washington Wiley, believed American consumers were suffering an epidemic of food poisoning strictly due to commercial food production.¹⁰³ At the time, food manufacturers were regularly preserving food with borax, formaldehyde, and copper sulfate.¹⁰⁴ Wiley's experiments demonstrated that consumers suffered weight loss, severe stomach cramps, and nausea along with a host of other symptoms ranging from mildly injurious to deadly due to poisonous food additives.¹⁰⁵

In 1906, muckraking journalist Upton Sinclair published "The Jungle," exposing in graphic detail the unsanitary conditions in Chicago's meat industry.¹⁰⁶ Wiley's experiments and

¹⁰³ Carrie A. Scrufari, Commentary, Substances Generally Recognized as Safe – Until They're Not: Challenges in Protecting the Food Supply in a Processed World, 36 Stan. Envtl. L.J. 219, 224 (2017).

¹⁰⁴ *Id.* at 225.

¹⁰⁵ Id.

¹⁰⁶ U.S. Food & Drug Admin., *Part I: The 1906 Food and Drugs Act and Its enforcement* (Apr. 24, 2019), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-i-1906-food-and-drugs-act-and-its-enforcement.

Sinclair's book sparked a media frenzy that caused sickened Americans to demand stricter regulations in the food supply.¹⁰⁷

Shortly after, Congress enacted the Pure Foods and Drugs Act of 1906 which gave the FDA enforcement authority over "adulterated" foods.¹⁰⁸ A food was deemed "adulterated" if it contained an "added poisonous or other added deleterious ingredient which may render such article injurious to health."¹⁰⁹ The 1906 Act was the first law regulating the food industry to protect consumers.¹¹⁰

B. The Food, Drug, and Cosmetic Act of 1938

The 1906 Act was largely successful, but the FDA had little enforcement authority to address newly emerging risks to the food supply. The Food, Drug, and Cosmetic Act of 1938 (FDCA) addressed the problem by permitting the FDA to set standards of identity and quality for food products.¹¹¹

However, the 1938 Act failed to properly ensure safety of food additives. Congress sought to impose stricter liability on food producers for adulteration of food by "acts of man" rather than nature under the assumption that producers had control over the former.¹¹² However, the language essentially created two standards for regulating adulterated substances, depending on whether they were added to the food product or not.¹¹³ An "added" substance adulterates food

¹⁰⁹ Id.

¹¹⁰ Id.

¹¹¹ *Id.* at 226-27.

¹¹³ *Id*.

¹⁰⁷ Scrufari, *supra* note 4, at 225.

¹⁰⁸ Id. at 226.

¹¹² Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 Ind. L. Rev. 305, 312 (2016).

if it is "injurious to health," but a non-"added" substance adulterates food only if "the quantity of such substance in such food ordinarily renders it injurious to health."¹¹⁴ Consequently, the 1938 Act failed to lead to an outright ban on added substances.¹¹⁵

C. The Food Additives Amendment of 1958

By 1958, food technology was developing rapidly, leading to the production of new food additives.¹¹⁶ The public became concerned that unsafe and untested additives were entering the food supply because the 1938 Act did not directly address food additives and failed to implement a pre-market approval process.¹¹⁷

To cure the regulatory gap, Congress enacted the Food Additives Amendment of 1958 (FAA) to the FDCA that "prohibited the use in food of additives which have not been adequately tested to establish their safety."¹¹⁸ A "food additive" is broadly defined to include "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."¹¹⁹

Any substance deemed a "food additive" under the FAA was subject to a stringent FDA pre-market approval process to ensure safety before being marketed to the public.¹²⁰ In passing

¹¹⁷ Id.

¹¹⁴ 21 U.S.C. § 342(a);

¹¹⁵ Carrie A. Scrufari, Substances Generally Recognized as Safe - Until They're Not: Challenges in Protecting the Food Supply in a Processed World, 36 Stan. Envtl. L.J. 219, 227 (2017).

¹¹⁶ Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 Ind. L. Rev. 305, 312 (2016).

¹¹⁸ 52 STAT. 1041 (1958) (codified as 21 U.S.C. § 348 (2012)).

¹¹⁹ 21 U.S.C. § 321(s) (2012).

¹²⁰ Dragich, *supra* note 13, at 312.

the FAA, Congress recognized that novel "additives" were nothing like traditional "food" and thus must be presumed unsafe until proven otherwise.¹²¹

1. The "Generally Recognized As Safe" (GRAS) Exception

However, the FAA defined "food additive" so broadly that it included common ingredients such as flour, sugar, and eggs.¹²² Having long been accepted as safe, it was important that these ingredients not be subject to the "food additive" pre-market review process.¹²³ Congress further recognized that scientific testing could demonstrate the safety of some artificial additives.¹²⁴

In an attempt to remedy the issue, Congress exempted "additives" if they were "generally recognized as safe," or GRAS.¹²⁵ An "additive" is GRAS if its use is generally recognized as safe by scientists knowledgeable about the safety of substances added to food and can be established through scientific procedures.¹²⁶ The exemption, before passage of the FAA, was largely meant to apply to ingredients commonly considered "safe additives" that had been used in foods without evidence of harm, such as salt and sugar.¹²⁷

i. Early Implementation

¹²³ Id.

¹²⁴ Id.

¹²⁶ Id.

¹²⁷ Id.

¹²¹ *Id.* at 312.

¹²² *Id.* at 313.

¹²⁵ Lauri J. Beyranevand, *Generally Recognized As Safe?: Analyzing Flaws in the FDA's Approach to GRAS Additives*, 37 VT. L. REV. 887, 898 (2013).

After passage of the FAA, the FDA worked to review, approve, and published a list of GRAS substances in use before 1958 but not GRAS.¹²⁸ Additionally, FDA reviewed informal opinion letters from the food industry requesting GRAS status for "additives" created after 1958, many of which were approved despite the lack of a pre-market approval process.¹²⁹

By 1970, President Nixon directed the FDA to reevaluate the safety of listed GRAS substances after a group of cyclamate salts had been found to cause bladder tumors in rats.¹³⁰ The purpose of the review was to evaluate each substance using modern standards and issue an affirmed GRAS or new "food additive" categorization.¹³¹ After an independent scientific organization reviewed 422 GRAS substances, the Committee on GRAS Substances recommended revoking GRAS status for 30 substances. An additional five were not harmful at current consumption levels but were still questionably unsafe.¹³² The FDA failed to take action on the Committee's findings.¹³³

In 1972, the FDA formalized the opinion letter practice through the GRAS affirmation petition (GAP) process, allowing individuals to petition the FDA to review and confirm GRAS status.¹³⁴ Although not mandatory, the GAP process was the primary mechanism for

¹²⁹ *Id.* at 315.

¹³¹ *Id*.

¹³⁴ *Id*.

¹²⁸ Martha Dragich, *supra* note 21, at 314.

¹³⁰ Food and Drug Administration, Docket No. FDA-1997-N-002, Substances Generally Recognized as SAFE (2016).

¹³²*Id*.; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-246, FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 21 (2010) "As of December 2009, FDA had affirmed the GRAS status of 17 of these 35 substances as GRAS..." According to GAO, FDA "could not readily explain why, even though almost 30 years had passed since the committee completed its work[,] FDA has not revoked the GRAS status of any of the 18 substances whose safety the committee questioned."

¹³³ Food and Drug Administration, Docket No. FDA-1997-N-002, Substances Generally Recognized as SAFE (2016).

manufacturers to protect themselves against the FDA enforcement actions.¹³⁵ Finally, in 1974, the FDA specified criteria for GRAS status, clarifying that a "general recognition of safety" could be demonstrated by either scientific procedures or by experience based on common use in foods before 1958.¹³⁶

ii. The 1997 Proposed Rule

In 1997, the FDA published a proposed rule that would create a new voluntary GRAS notification procedure to replace the GAP process.¹³⁷ Although never finalized, the proposal has been in force as an interim procedure since 1997.¹³⁸

The voluntary notification procedure permits any person to submit a "GRAS exemption claim" which notifies the FDA that a proposed use of a substance is GRAS.¹³⁹ In replacing the GAP process, the FDA hoped to streamline the notification procedure and encourage individuals to request self-determined GRAS status affirmation.¹⁴⁰ Instead, the 1997 proposal shifted GRAS evaluations from independent FDA review to self-determined GRAS producers.¹⁴¹ The GAP process required self-determined GRAS producers to submit complete data to the FDA, but the

¹³⁶ *Id*.

¹³⁷ Id.

¹³⁹ Id.

¹⁴¹ *Id*.

¹³⁵ *Id*.

¹³⁸ See Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570)..

¹⁴⁰ Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 317 (2013).

notification process required only a summary review.¹⁴² Thus, the FDA makes no independent review of safety nor data claimed to establish safety.¹⁴³

Furthermore, the 1997 proposal emphasizes that the *safety* standard for food additives and GRAS substances is the same, but GRAS additionally required *common knowledge* of the safety of a use or substance.¹⁴⁴ However, it also broadened the "common knowledge" element by expanding the acceptable types of technical evidence of safety.¹⁴⁵ Specifically, that "general recognition of safety through scientific procedures be based upon generally available and accepted scientific data, information, methods, or principles, which ordinarily are published."¹⁴⁶ The new language elevated the role of *unpublished* studies, data, information, and methods from mere corroboration to primary support. ¹⁴⁷

D. Modern Implications of the FAA and GRAS Exception

The FAA was enacted to ensure food additives were subject to the high safety standards of the pre-market review process. But the GRAS exemption has unraveled the intended regulatory protections. The GRAS exemption permits producers to self-determine the GRAS status of additives and immediately market them to the public. The 1997 proposal further weakened the FDA's role in evaluating self-determined GRAS substances by requiring only summary evidence of safety and elevating the role of mere corroboration in establishing safety. As a result, the FDA has less information about additives present in the food supply than ever

¹⁴⁷ Id.

¹⁴² *Id*.

¹⁴³ *Id*.

¹⁴⁴ Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,940 (proposed Apr. 17, 1997).

¹⁴⁵ *Id*.

¹⁴⁶ Id.

before and consequently, is ill-equipped to protect consumers from the exact harms the FAA sought to prevent.

II. Nanotechnology

Nanotechnology is an emerging scientific discipline with a variety of applications in numerous industries, including medical diagnosis and treatment, energy production, electronics, automotive and aerospace materials, and food and agriculture.¹⁴⁸ The promise of innovation has driven commercial development of nanotechnology dramatically over the past ten years.¹⁴⁹

Nanotechnology is the manufacture and use of materials on a nanometer size scale.¹⁵⁰ One nanometer is one-billionth of a meter (1 x 10⁻⁹ m) and engineered nanomaterials (ENPs) are about one to 100 nanometers in size.¹⁵¹ In comparison, the width of a human hair is about 80,000 nanometers wide.¹⁵² Nanomaterials can exist in three forms: (1) nanoparticles, where all three external dimensions are at the nanoscale; (2) nanotubes, where two dimensions are at the nanoscale; and (3) sheets, where only one dimension is at the nanoscale.¹⁵³ Nanomaterials can be "fixed" in a matrix, such as food packaging materials.¹⁵⁴ Other products contain "free" nanomaterials that are separate from each other, such as cosmetics and personal care products.¹⁵⁵

¹⁴⁸ CHAUDHRY ET AL., *supra* note 1, at 143.

¹⁴⁹ Id.

¹⁵⁰ *Id.* at 1.

¹⁵¹ Id. at 1; Katharine Van Tassel, Regulating in Uncertainty, U Chi Legal F 433, 441 (2013).

¹⁵²VAN TASSEL, *supra* note 52, at 445.

¹⁵³ CHAUDHRY ET AL., *supra* note 1, at 2.

¹⁵⁴ *Id.* at 3.

¹⁵⁵ VAN TASSEL, *supra* note 52, at 444.

In theory, any particulate matter can be produced in nanoform by either grinding down larger materials or assembling atoms to build nanoscale particles.¹⁵⁶ Consequently, the chemical nature of a nanomaterial can be inorganic, organic, or hybrid in nature.¹⁵⁷ Furthermore, not all nanomaterials must be manufactured.¹⁵⁸ Some are derived from natural sources such as montmorillonite, a clay obtained from volcanic ash, that has a natural nanoplate structure and is used as a nanofiller in food packaging applications.¹⁵⁹

The physical properties of ENPs are fundamentally different than their normal sized particles, including differences in toxicity, bioaccumulation, persistence, chemical, magnetic, electrical, explosive, and optical characteristics.¹⁶⁰ The ability to change the properties of particles has the potential to improve material properties, develop new functionalities, and reduce the amount of substances required for a function.¹⁶¹

A. Applications in the Food Industry

Nanotechnology has potential applications in numerous industries, but many experts believe it has the potential to revolutionize the agricultural-food sector, from food packaging and smart labels to nanoscale carriers that facilitate the delivery of nutrients.¹⁶²

1. Nanostructured Food Products & Nanomaterials in Food

¹⁵⁷ Id.

¹⁵⁸ Id.

¹⁵⁹ Id.

¹⁶² *Id.* at 4.

¹⁵⁶ CHAUDHRY ET AL., *supra* note 1, at 2.

¹⁶⁰ VAN TASSEL, *supra* note 52, at 446.

¹⁶¹ CHAUDHRY ET AL., *supra* note 1, at 3.

Producers claim that nanostructured foods and foods infused with nanomaterials have greater nutritional and health benefits, new or improved tastes, textures and flavors, and lower amounts of additives such as sugar, salt, fat, artificial preservatives, colors, and flavors.¹⁶³

Nanostructured foodstuffs are produced through nanoscale processing methods that claim to develop new tastes, textures, consistency, and emulsion stability.¹⁶⁴ For example, a nanostructured mayonnaise composed of nanomicelles containing nanodroplets of water is a low-fat product that is as 'creamy' as the full-fat alternative, offering the consumer a 'healthy' option without compromising taste or texture.¹⁶⁵ Nanoscale processing can also produce nanoencapsulated food additives and supplements for the purpose of preserving additives, masking undesirable flavors, controlling release, and enhancing uptake in the body.¹⁶⁶ Nanosized carriers enhance delivery of nutrients or other substances currently available in the form of supplements and health food products containing nanoforms of minerals, vitamins, and antioxidants.¹⁶⁷

Little information is available about the nanomaterials used in food, but available data suggests manufacturers incorporate a variety of inorganic, organic, and hybrid ENPs.¹⁶⁸ Organic materials include a wide range of nanostructured or nanoencapsulated vitamins, antioxidants, colors, flavors, and preservatives.¹⁶⁹ Additional ENPs include metals such as iron, silver,

¹⁶⁵ *Id*.

- ¹⁶⁸ Id.
- ¹⁶⁹ Id.

¹⁶³ *Id*.

¹⁶⁴ *Id.* at 9.

¹⁶⁶ *Id.* at 9-10.

¹⁶⁷ CHAUDHRY ET AL., *supra* note 63, at 10.
calcium, and magnesium and non-metals such as silicates.¹⁷⁰ Some of the nanomaterials in use are approved food additives, such as silica and titanium dioxide.¹⁷¹

2. Engineered Nanomaterials in Food Packaging

Food packaging is currently the largest application of nanotechnology in the food industry with the potential to enhance security and safety of foods during processing, transportation, and storage.¹⁷²

Food contact materials (FCMs) are infused with ENPs to improve flexibility and gas barrier properties, and monitor temperature and moisture stability.¹⁷³ For example, nanoclay additives are formulated into thermoplastics and act as a gas barrier.¹⁷⁴ Active FCMs incorporate nanoparticles (such as silver, zinc oxide, and magnesium oxide) which act as antimicrobial barriers, keeping food fresher for longer periods of time.¹⁷⁵ Nanoparticles of titanium dioxide provide UV protection, and nanocoatings of silica act as self-cleaning surfaces that help maintain hygienic conditions.¹⁷⁶

Some FCMs also incorporate smart labels developed with nanosized sensors that monitor the condition of food during transport and storage.¹⁷⁷ Intelligent packaging can provide safety

¹⁷¹ Id.

¹⁷³ *Id.* at 10.

¹⁷⁴ *Id*.

¹⁷⁵ *Id.* at 11.

¹⁷⁶ *Id.* at 10-11.

¹⁷⁰ Id.

¹⁷² CHAUDHRY ET AL., *supra* note 63, at 10-11.

¹⁷⁷ CHAUDHRY ET AL., *supra* note 63, at 11.

indicators to monitor quality of vacuum sealed packages by detecting leaks, freeze-thawrefreezes, and deterioration of foodstuffs.¹⁷⁸ In the future, smart labels would warn consumers if food is contaminated or has gone bad.¹⁷⁹

B. Health and Safety Concerns

The potential applications of nanotechnology to the food industry has sparked as much excitement as it has concern. Studies on the health and safety effects of nanomaterials are limited, but the available research suggests risks associated with exposure to nanoparticles are related to three key characteristics: (1) small size, (2) high surface area, and (3) unique properties.

First, nanoparticles are small. This means that ENPs have the ability to penetrate cellular barriers where larger sized particles would normally be restricted.¹⁸⁰ Nanomaterials would most likely enter through the gut wall that normally allows uptake of dietary nutrients and prevents passage of larger materials.¹⁸¹ The concern is that ENPs may allow insoluble or biopersistent particles to pass through the barrier, resulting in higher absorption and bioavailability of not only ENPs in the body, but other toxic substances as well.¹⁸² Furthermore, nanoparticle's small size also has the potential to clog phagocytes, scavenger cells that eliminate foreign substances in the

¹⁷⁹ Id.

¹⁸⁰ *Id.* at 13.

¹⁸² *Id*.

¹⁷⁸ Id.

¹⁸¹ CHAUDHRY ET AL., *supra* note 63, at 14.

body.¹⁸³ If phagocytes are clogged with ENPs, foreign particles and bacteria can invade the body, causing an HIV-like effect.¹⁸⁴

Second, nanoparticles have greater surface area than their conventional equivalents, and thus, enhanced bioreactivity.¹⁸⁵ The benefit of enhanced bioreactivity is that a small amount of ENPs can provide a similar level of functionality to the bulk equivalent (like 'creamy' low-fat mayonnaises).¹⁸⁶ However, enhanced bioreactivity also poses risk for proportionally greater toxic impact.¹⁸⁷ For example, titanium dioxide at the macroscale is harmless, but at nano-size, its pulmonary toxicity increases due to increased surface area.¹⁸⁸

Finally, ENPs are hard to predict. Not only are their properties, and thus behavior and biological interactions, fundamentally different from their bulk equivalents, but it is difficult to predict the location of ENPs in the body and the effect of their properties in different environments.¹⁸⁹ The sheer number of nanomaterials, uses, and interactions likely have a substantial effect on absorption, distribution, metabolism, and body elimination profile.¹⁹⁰

Science is working towards understanding how the physiochemical nature, level of uptake, translocation, and bioavailability of ENPs effects the body.¹⁹¹ But risk evaluation also depends on the concentration of nanomaterials in a food product and the amount and frequency

¹⁸⁷ Id. at 13.

¹⁸³ Katharine Van Tassel, Regulating in Uncertainty, U. CHI. LEGAL F. 433, 448-49 (2013).

¹⁸⁴ Id. at 449.

¹⁸⁵ *Id.* at 447.

¹⁸⁶ CHAUDHRY, *supra* note 80, at 9.

¹⁸⁸ Tassel, *supra* note 84, at 488.

¹⁸⁹ Id.

¹⁹⁰ QASIM CHAUDHRY ET AL., NANOTECHNOLOGIES IN FOOD 13 (Qasim Chaudhry et al. eds., 2d ed. 2017).
¹⁹¹ Id.

of consumption.¹⁹² As with any emerging innovation, there are more unknown than known risks. However, the little information available suggests exposure to nanoparticles may have unforeseen consequences, highlighting the importance that the safety of nanotechnology be adequately addressed.

III. Nanofoods and FDA Regulatory Framework

The FDA is familiar with the promise, risk, and uncertainty that accompanies emerging technologies, but nanotechnology in particular poses unique regulatory challenges. The first section explains why the ambiguous definition of "nanomaterials" is the preliminary hurdle in implementing effective nanotechnology regulation.

A. Defining "Nanomaterials"

The preliminary step in drafting any regulation is defining what exactly is being regulated. But defining "nanotechnology" is exceedingly difficult, not only because the science is still developing, but also because the technology straddles so many different disciplines, applications, and forms. Consequently, scientists and lawmakers cannot agree upon a definition that is both scientifically credible and legally plausible. ¹⁹³ Regardless, many countries have put forth their own definitions of "nanotechnology" in attempt to regulate the nanoproducts that will inevitably appear in the market.¹⁹⁴

In response to a U.S. Government Accountability Office (GAO) report urging the FDA to strengthen its oversight of nanomaterials, the FDA issued voluntary guidance documents to help

¹⁹² *Id.* at 14.

¹⁹³ Gary E. Marchant et al., *Big Issues For Small Stuff: Nanotechnology Regulation and Risk Management*, 52 JURIMETRICS J. 243, 260 (2012).

¹⁹⁴ *Id.* at 53.

industry consider whether an FDA-regulated product involves nanotechnology.¹⁹⁵ The definition is intended to be specific enough to identify nanomaterials, but also broad enough to address characteristics thought to implicate safety, effectiveness, public health, and regulatory status of nanoproducts.¹⁹⁶

The guidance document definition defines what is and is not nanotechnology by addressing particle dimensions and dimension-dependent properties of nanomaterials.¹⁹⁷ To determine whether an FDA-regulated product involves the application of nanotechnology, "FDA will ask whether a material or end product is engineered to:

- have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm), [and]
- (2) exhibit properties or phenomena, including physical or chemical properties or biological effects that are attributable to its dimensions, even if the dimensions fall outside the nanoscale range, up to 1000 nm."¹⁹⁸

The definition takes into account both quantitative (numerical dimension) and qualitative (dimension-dependent properties) characteristics thought relevant for risk assessment that are different from non-nanomaterials.¹⁹⁹ However, qualitative criteria defining nanoscale dimensions, even approximately, is legally necessary but scientifically problematic.

¹⁹⁵ FDA'S APPROACH TO REGULATION OF NANOTECHNOLOGY PRODUCTS, https://www.fda.gov/science-research/nanotechnology-programs-fda/fdas-approach-regulation-nanotechnology-products (last visited Jan. 25, 2019).

¹⁹⁶ Chaudhry, *supra* note 1 at 29.

¹⁹⁷ Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, U.S. FOOD & DRUG ADMIN. (June 2014), https://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm#points.

¹⁹⁸ Id.

¹⁹⁹ Chaudhry et al., *supra* note 1, at 24.

First, there is no standard method for measuring nanoparticle size.²⁰⁰ The FDA guidelines for measuring material properties are developed for materials with larger external dimensions.²⁰¹ Consequently, FDA must adopt its technical guidelines for measuring physiochemical properties to accommodate nanomaterials.²⁰² Furthermore, many available measurement methods provide only an average external dimension because it is incredibly difficult to accurately measure particle dimensions at such small scale.²⁰³ To complicate the matter, a particles diameter not only depends on the particle shape, but also how the diameter is measured.²⁰⁴ Because different scientific measurement methods can provide significantly different dimensional values, an applicable legal standard based on strict quantitative dimensions is not yet possible.²⁰⁵

Unlike the quantitative elements, the guidance documents purposely leave room for interpreting the qualitative criteria that define nanomaterial as a particle with "properties that are attributable to its dimensions."²⁰⁶ But legal interpretation will eventually require specification of the qualitative element in order to actually identify a nanomaterial for regulatory purposes.

The problem is that there is no direct, material-independent relationship between particle size and novel effects or functions.²⁰⁷ The size at which a particle starts to exhibit special properties may change for the same material depending on the environment and interactions with

²⁰⁴ Id.

²⁰⁰ Marchant et al., *supra* note 94.

²⁰¹ Chaudhry et al., *supra* note 1, at 32.

²⁰² Id.

²⁰³ Id.

²⁰⁵ Id.

²⁰⁶ Chaudhry, *supra* note 49, at 33.

²⁰⁷ Id.

other materials.²⁰⁸ Furthermore, it can be unclear when the nano-related property is sufficiently pronounced or different from the macro-related property, making it difficult to distinguish between nanoscale and macroscopic properties.²⁰⁹ If scientists disagree about when a property is characteristic of the nanoscale and when a property is sufficiently novel to identify a nanomaterial, it will be difficult for lawmakers to effectively apply the qualitative criteria.²¹⁰

Because the quantitative data is difficult, if not impossible, to obtain and the qualitative criteria is highly case dependent, finding a sufficient legal definition of "nanomaterial" for regulatory purposes is problematic. Regulation requires bright-line criteria, but nanomaterials appear to have few distinguishable characterizations. Furthermore, imposing a bright-line definition would likely result in under-inclusive regulations. Similar products, either through strategic or fortuitous variations, could lie opposite the dividing line between regulation and non-regulation.²¹¹

Although the FDA guidance document definition of "nanomaterials" is not binding, it highlights the significant challenges the FDA faces in developing effective nanotechnology regulation.

B. Nanomaterials as "Food Additives" Under the FAA

Because the FDA has issued no binding regulations, nanomaterials are regulated under current legal authority. The wide variety of applications, materials, and intended uses of nanomaterials tests the limits of current regulatory frameworks. Regardless, the FDCA and FAA are generally well equipped to encompass the variety of nanotechnology applications in the food

²⁰⁸ Marchant, *supra* note 101, at 260.

²⁰⁹ Chaudhry, *supra* note 49, at 31.

²¹⁰ *Id.* at 33-34.

²¹¹ Marchant, *supra* note 101, at 260.

industry due to their general nature, designed to "flexibly accommodate products made with new technologies or containing new kinds of materials."²¹²

The FDCA defines "food" as "articles used for food or drink for man or other animals... [and] articles used for components of any such article," later clarifying that "food" also included substances migrating to food from FCMs.²¹³ Thus, the FDCA gave FDA authority over whole foods, processed foods, products of artificial origin, as well as substances unfit for consumption and food packaging materials.²¹⁴ Although arguably overbroad in some cases, "food" under the FDCA likely includes the vast majority of nanostructured food products and nanomaterial additives and packaging by virtue of becoming "components" of food. Thus, the FDCA gives FDA regulatory authority over the majority of nanomaterials that could possibly be ingested by humans.²¹⁵

1. What is a "Food Additive"?

Determining whether a nanomaterial is a "food additive" under the FAA is surprisingly complex because the definition is both broad and narrow. Consequently, nanomaterials in food are likely to be "food additives," but also likely to be subject to any of the major exceptions.

Under the FAA, a "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."²¹⁶

²¹⁶ 21 U.S.C. §321(s).

²¹² Id.

²¹³ 21 U.S.C. § 321(f) (2011); 21 CFR §170.3(m) (2018).

²¹⁴ Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 320 (2016).

²¹⁵ See generally Substances Generally Recognized as Safe (GRAS), U.S. FOOD & DRUG ADMIN. (Sept. 6, 2019), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.

If a substance falls under this definition, it is subject to FDA pre-market review process that requires the applicant to file a petition to FDA with scientific evidence demonstrating that the additive will be safe for use in food.²¹⁷ The petition must include the intended technical effect, the method of analysis in food, and full reports of all safety studies.²¹⁸

In reviewing an application, FDA will consider the potential cumulative effect on consumers, taking into account related substances, probability of consumption, and safety factors.²¹⁹ If FDA determines the additive is safe, the agency will publish an approval notice and the company can start using the ingredient in food under specific regulations approved by the FDA.²²⁰ However, if FDA denies the petition, the additive is considered illegal.²²¹

The FAA's broad "food additive" definition coupled with the stringent pre-market approval requirement is designed to ensure novel food additives are safe for consumption. In the application of nanofoods, it is necessary that "food additive" be defined unusually broadly.

First, it includes common ingredients such as sugar and salt that have been used for centuries and not usually considered an "additive."²²² However, any molecule can have a nanoparticle counterpart with very different properties and effects than its bulk equivalent. If the definition did not include common ingredients, their equivalent nanoparticles may not be considered an additive. But under the current definition, a nanoparticle of sugar is an "additive" with the potential to be subject to pre-market review.

²¹⁸ Id.

²¹⁹ Id.

²²⁰ Id.

²²¹ *Id*.

²¹⁷ Substances Generally Recognized as Safe (GRAS), 62 Fed. Reg. 18938, FDA-1997-N-0020 (Oct. 17, 2016).

²²² Thomas G. Nelter, et al., *Navigating the U.S. Food Additive Regulatory Program*, 10 COMPREHENSIVE REVIEWS IN FOOD SCI. AND FOOD SAFETY 342, 343 (2011).

Second, it includes "food contact substances" that are not intended to become part of the food, but become components of food indirectly.²²³ Therefore, "food additive" includes thousands of substances in food packaging, processing, and storing.²²⁴ Consequently, nanomaterials used in food packaging are "additives" as well.

The definition of "food additive" under the FAA is well designed to encompass new and novel food additives as unique as nanomaterials despite the lack of an accepted definition of "nanomaterials."

However, the definition is just as narrow as it is broad. The statute includes three broad exceptions. First, substances "generally recognized as safe" among qualified experts are excluded from the definition and thus, not a "food additive."²²⁵ Second, substances approved by the FDA before enactment of the FAA were grandfathered in to the regulatory program.²²⁶ Third, Congress excluded specific substances, including color additives (1960) and dietary supplements (1994), and established distinct regulatory programs and standards for them.²²⁷

Not only is it difficult to determine whether a "food additive" falls into an exception, but the same substance may fall into multiple categories depending on its intended use.²²⁸ Although the exceptions appear rather limited, the GRAS exception is primarily responsible for unraveling the regulatory protections for food additives.

C. The GRAS Exception

²²³ Id.

²²⁴ Id.

²²⁵ Id.

²²⁶ Id. at 344.

²²⁷ Id.

²²⁸ Id.

Nanomaterials are precisely the type of novel "food additive" Congress intended to subject to pre-market testing. But the GRAS exception leaves a gaping loophole in food additive regulation. The 1997 proposal implemented a voluntary notification process and weakened the GRAS standard, permitting the food industry to experiment on the public – the precise concern that the FAA sought to remedy.²²⁹ Consequently, nanomaterials can masquerade as GRAS rather than being FDA approved via the statutory food additive petition process.²³⁰

In the absence of the GRAS exception, nanomaterials in food applications would be subject to traditional pre-market approval procedures. Instead, the current standards and procedures subject the American public to potentially dangerous additives and leave the FDA with no way of knowing the extent to which nanomaterials are marketed in the food supply.

1. The Not-So GRAS Standard

A GRAS substance must satisfy a "safety" standard and a "common knowledge" element.²³¹ However, many traditional safety tests are inapplicable to nanotechnology, suggesting it is currently no possible for nanomaterials to satisfy the required "safety" standard.²³² If nanomaterials cannot meet GRAS safety standards, then the additional "common knowledge" element cannot be satisfied either. Regardless, nanomaterials continue to slip through the GRAS system and into consumers mouths.

i. "Safety" Standard

²²⁹ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

²³⁰ Id.

²³¹ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

²³² Id.

GRAS substances are "generally recognized, among experts qualified by scientific training and experience to evaluate the safety as having been adequately shown... to be safe under conditions of their intended use."²³³ "Safety" is determined through the same scientific procedure standard as employed in the pre-market review process for "food additives."²³⁴ The safety determination "shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information."²³⁵ While the safety standard appears sufficient, emerging nanotechnology reveals the scientific limitations for testing nanomaterials safety.

First, the FDA's current scientific standards for testing GRAS substances cannot address emerging risks.²³⁶ Because nanomaterials can alter the bioavailability and level at which toxic effects occur in the body, the FDA's standard toxicological guidance may not address "known toxicological endpoints" for certain nanoparticles.²³⁷ In these cases, the FDA states the food industry has the responsibility to "develop appropriate protocols to address particular safety issues."²³⁸

Furthermore, the FDA concedes that ensuring safety of nanomaterials would require testing different than traditional safety tests for their bulk counterparts.²³⁹ Most notably,

²³³ 21 U.S.C. § 321(s).

²³⁴ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

²³⁵ 21 C.F.R. §170.30(b).

²³⁶ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

²³⁷ Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, FOOD & DRUG ADMINISTRATION 15-16 (Jun 2014), https://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm#points.

²³⁸ Id.

²³⁹ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

traditional toxicology tests used to assess nanomaterials have reported significant variability.²⁴⁰ Validation methods of traditional toxicology tests would be required to ensure the results are meaningful and appropriate to the safety of food substances.²⁴¹

Because standard safety guidance is inapplicable and traditional safety tests are inadequate at testing the safety of nanoparticles, nanomaterials cannot possibly meet the safety standard required for GRAS substances.

ii. "Common Knowledge" Standard

Unlike "food additives," GRAS substances must also satisfy a common knowledge requirement.²⁴² "Generally recognized" includes two elements: (1) generally available data and (2) consensus among experts.²⁴³ Peer-reviewed publications demonstrate common knowledge. However, the 1997 proposal allowed other means such as secondary scientific literature, expert panels, and opinions from scientific authorities.²⁴⁴

Regardless of weakened scientific standards, it is not possible for a nanomaterial to satisfy the common knowledge element because testing cannot prove the requisite "safety" of nanomaterials. Therefore, it is not possible for a nanomaterial to be "generally recognized" as safe. Experts are just starting to understand the effects of nanomaterials, let alone the potential long-term risks associated with regular and frequent consumption. Even FDA concedes it does

²⁴⁰ Id.

- ²⁴³ Id.
- ²⁴⁴ Id.

²⁴¹ *Id*.

²⁴² Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

not know of any generally available safety data sufficient to serve as the foundation for a GRAS determination.²⁴⁵

FDA's guidance document appears to conclude that nanomaterials cannot possibly be GRAS substances. But despite failing both the safety and common knowledge requirements, nanomaterials have made their way to the market disguised as GRAS.

2. The Voluntary GRAS Notification Procedure

The "food additives" process is a long, windy walk through the woods, but selfdetermining GRAS status is a highway to market. Alternatively, filing a GRAS exemption claim through FDA is a detour that could potentially lead to a dead end.

FDA's the current GRAS procedure incentivizes the industry to circumvent FDA notification. When choosing between FDA notice with the possibility rejection or no FDA notice, industry will choose the latter. Even though an independent GRAS determination must comply with FDA "safety" and GRAS "common knowledge" standards, manufacturers are under no obligation to notify FDA of their grounds for GRAS status before marketing the substance.²⁴⁶ If questioned by FDA, a GRAS determination is easier to defend due to diluted scientific standards.²⁴⁷

The alternative option is to notify FDA of a self-determined GRAS substance. The producer would file a GRAS exemption claim that includes a "succinct" the basis for the GRAS determination and a statement that information supporting the GRAS determination is available

²⁴⁵ Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, U.S. FOOD & DRUG ADMINISTRATION 15-16 (June 2014), https://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm#points.

²⁴⁶ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

²⁴⁷ Id.

for FDA review and will be sent upon request.²⁴⁸ FDA will then respond with (1) "no questions," (and therefore, it is implied that the substance may be used in food without further FDA review), (2) the notice is insufficient, or (3) FDA has ceased to evaluate the GRAS notice at the company's request.²⁴⁹

When FDA rejects a GRAS notice, a letter explaining the safety concerns is sent to the company and published on FDA's website. However, a company may withdraw the notice and ask FDA to cease further review. In this case, FDA does not publish the questions prompting concern, but evidence shows that companies may continue to market the substance for use in food.²⁵⁰

Conclusion

Congress has recognized the inherent dangers to consumers of industrially produced foods full of novel and artificial additives. The FAA implemented a regime requiring strict oversight of additives presumed unsafe. Novel innovations like nanotechnology reveals the FAA is surprisingly flexible in its intended application despite inherent and unique challenges in regulating nanomaterials.

However, the GRAS exception is a loophole swallowing Congress's original intention. Consequently, most novel food products, including nanomaterials reach the market without FDA's safety approval. The system leaves FDA without any comprehensive information about additives actually in use. Technology is developing at an exponential rate and if FDA does not regain knowledge and control over what goes in our food, we may never find out.

²⁴⁸ Id.

²⁴⁹ Id.

²⁵⁰ Substances Generally Recognized as Safe (GRAS), FDA-1997-N-002.

<u>A Challenge to International Regulation of Intersex Female</u> <u>Athletes: The Limits of a Male-Female Classification in Sports</u>

Dejaih L. Johnson²⁵¹

Abstract

The history of discrimination against the disabled, intersexual, asexual, and transgender individuals' rights, contributes to the importance of scrutinizing policy in each of these areas. In 2018, an international federation (governing athletics policies) promulgated a regulation that excluded female athletes from competition who did not fit within the "biological definition" of female. By misallocating the risk and discriminating against female athletes who more accurately identify as intersex, the regulation violates the core values of the federation's controlling agency. There is a tremendous need for reliable and sound science in this field before policies to limit women's participation are put in place. Instead, the federation has relied on a questionable quantitative research study conducted by the British Sports Medicine Journal and continues to implement its problematic regulation.

This note will address the federation's female classification regulation and its ubiquitous violation. Beginning first with the assertion that sex is better understood on a spectrum and introduction of intersexuality, there will be exploration into the history of sex testing and previous classifications regulating female athletic competition. After discussing the framework of the federation's governing agency, this note will conclude the regulation is a violation of the spirit and intent of the agency's core document and ideals.

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Introduction

In many areas, gender equality has begun to gradually improve. Recently we have seen women make great strides in everything from education to maternity morality. Nevertheless, understandings in politics and public life seem to be improving, the sports industry has continued to lag behind. With its binary classification of gender, sport regulations remain susceptible to discriminatory practices and reinforcement of outdated ideals. But since the turn of the twentieth century, these regulations have extended beyond the male-female dichotomy and have gone insofar as excluding from competition women who are not "feminine enough".

The International Association of Athletics Federations (IAAF) is the international governing body for professional level athletics and track and field.²⁵² In 2019, the IAAF updated their promulgated rules that exclude female athletes who do not fit neatly within a binary classification.²⁵³ Among other things, the regulation excludes from certain restricted events female athletes who are classified to have disorders of sex development (DSD), or more precisely identify as intersex.²⁵⁴ Intersexuality can include many different medical conditions, but the IAAF has focused its efforts to exclude females with certain DSD.²⁵⁵ In particular, those that result in naturally occurring high levels of testosterone.²⁵⁶ Reliant upon a British medical study, the IAAF believes these DSD give certain female athletes a significant performance enhancement.²⁵⁷

²⁵² INT'L ASS'N OF ATLHETICS FEDERATIONS, *About the IAAF*, https://www.iaaf.org/about-iaaf (last visited Sep. 27, 2019).

²⁵³ INT'L ASS'N OF ATLHETICS FEDERATIONS, *Eligibility Regulations for the Female*

Classification (Athletes with Differences of Sex Development), 1-3 (May 1, 2019), https://www.iaaf.org/about-iaaf/documents/rules-regulations.

²⁵⁴ *Id.* at 2-3.

²⁵⁵ Id.

²⁵⁶ *Id.* at 2.

²⁵⁷ Press Release, INT'L ASS'N OF ATHLETICS FEDERATIONS, IAAF Publishes Briefing Notes & Q&A on Female Eligibility Regulations (May 07, 2019), https://www.iaaf.org/news/press-release/questions-answers-iaaf-female-eligibility-reg (last visited Sep. 27, 2019); see also INT'L ASS'N OF ATHLETICS FEDERATIONS, *Eligibility Regulations*

Aside from the obvious human rights concerns, the IAAF regulation runs contrary to the most global fundamental beliefs within sport culture. The World Anti-Doping Code (Code) is the core governing document that provides the framework for which sport organizations and public authorities promulgate policies, rules, and regulations.²⁵⁸ The Code operates around three ideals: fairness, protecting the health of the athlete, and maintaining the "spirit of sport".²⁵⁹ The IAAF argues to preserve these ideals, the federation must exclude intersex female athletes.²⁶⁰ However, both on its face and in its application, the IAAF's eligibility regulations run contrary to the spirit, intent, and purpose at which the Code functions. The IAAF regulation has led us to question if sports will be a place that discriminates, that arbitrates from a place of fear, that protects a western world ideal of femininity and conforming above all else, or if it will side with inclusivity and understanding.

I. Sex versus Gender Distinction

a. Sex

Often people use the terms sex and gender interchangeably. However, the two terms differ substantially. Normally, the sex of an individual represents the sum of the body's sexual or reproductive system.²⁶¹ Sex is a biological trait that is determined by the specific sex chromosomes inherited from one's parents.²⁶² Male sex is determined by the presence of the Y

for the Female Classification (Athletes with Differences of Sex Development) Explanatory Notes/Q&A, 1-3 (May 01, 2019).

²⁵⁸ U.S. ANTI-DOPING AGENCY, *World Anti-Doping Code (WADA)*, https://www.usada.org/about/world-anti-doping-code/ (last visited Sep. 27, 2019).

²⁵⁹ Matthew Hard, *Caught in the Net: Athletes' Rights and the World Anti-Doping Agency*, 19 S. CAL. INTERDISC. L. J. 533, 535 (2010).

²⁶⁰ IAAF Regulation, *supra* note 3.

²⁶¹ Shawn M. Crincoli, You Can Only Race if You Can't Win? The Curious Cases of Oscar Pistorius & Caster Semenya, 12 TEX. REV. ENT. & SPORTS L. 133, 160 (2011).

²⁶² Krista Conger, *Of mice, men and women: Making research more inclusive*, STANFORD MEDICINE, https://stanmed.stanford.edu/2017spring/how-sex-and-gender-which-are-not-the-same-thing-influence-our-health.html (last visited Feb. 14, 2019).

chromosome while those with solely X chromosomes are usually female.²⁶³ There are, however, variants like XXY or XYY which are typically male, but different exceptions and challenges arise when the sexual system is not fully aligned.²⁶⁴

Given the difficulties in determining the sex of an individual by their chromosomal makeup, other measures are generally used. Currently, there are at least six criteria to determine an individual's sex: (1) sex chromosome consultation; (2) sex hormonal pattern; (3) gonadal sex (i.e. testes or ovaries); (4) internal sex organs; (5) external genitalia; and (6) secondary sexual characteristics.²⁶⁵ At each stage there are an infinite number of molecules involved and various makeups can result in one becoming male or female.²⁶⁶ This makes determining the sex of an individual extremely difficult, and atypical cases are beginning to become more frequent. Consequently, leading to an increased necessity for a very careful and confidential approach to sex testing.

b. Gender

On the other hand, gender refers to one's identity and is socially, culturally, and personally defined.²⁶⁷ Gender accounts for how individuals see themselves, are perceived by others and expected to behave, and their interactions with others.²⁶⁸ It therefore has little to do with your biological makeup, but most often, the entirety of one's person aligns²⁶⁹. That is to say: The insides match the outside. But this is not always the case. Increasingly the medical community is realizing that both men and women exhibit a spectrum of gender traits and sexual makeup that is

²⁶³ Id.

²⁶⁴ Id.

²⁶⁵ Daniel Gandert et al., *The Intersection of Women's Olympic Sport and Intersex Athletes: A Long and Winding Road*, 46 IND. L. REV. 387, 393-394 (2013).

²⁶⁶ Id.

²⁶⁷ Conger, *supra* note 12.

²⁶⁸ Id.

²⁶⁹ Id.

inconsistent with the cut and dry binary groups of male and female.²⁷⁰ In some cases, treating sex as a binary choice between male and female is physiologically incorrect.

c. Intersexuality

The identification of an individual as either male or female seems fairly simple at the outset. Nevertheless, identification can be complex and at the turn of the twentieth century the medical community began to account for this.²⁷¹ "Intersexuality is the term used for individuals who are neither strictly biologically male or female" due to a variety of conditions affecting the person's reproductive or sexual anatomy.²⁷² Many different conditions produce intersexuality, but the most common is that the person has a chromosomal make-up that differs from how he or she appears.²⁷³ Illustrative of this is one who has XY chromosomes, typically making them male, but something prevents the body from aligning with that of a male. If the individual has Androgen Insensitivity Syndrome (AIS), the body cannot properly metabolize androgens and lacks the ability to synthesize and develop from male hormones.²⁷⁴ Since AIS can produce an array of external appearances, some individuals appear outwardly one sex and therefore grow up without knowledge of his or her condition.²⁷⁵

Like gender and sex, intersexuality and disorders of sex development are often used interchangeably. Many people in the community reject the usage of DSD due to its use of the word "disorder". Instead, they use "intersex" since, as the Intersex Society of North America (ISNA) has stated, "Intersex itself is not a disorder, rather a variation."²⁷⁶ Out of respect for the

²⁷⁰ Id.

²⁷¹ What's the history behind the intersex rights movement?, INTERSEX SOCIETY OF NORTH AMERICA, http://www.isna.org/faq/history (last visited Sept. 26, 2019).

²⁷² Crincoli, *supra* note 11.

²⁷³ Id.

²⁷⁴ Id.

²⁷⁵ Id.

²⁷⁶ Conger, *supra* note 12.

those in the community and its allies, DSD will be used sparingly throughout the remainder of this note and "intersex" will be used in its place.

Intersexuality itself is not one condition but instead encompasses a number of different forms. Intersex is a general term used for a variety of conditions in which a person is born with a reproductive or sexual anatomy that does not fit within the typical definitions of male or female. The ISNA has identified at least sixteen conditions that qualify an individual as intersex: (1) 5alpha reductase deficiency; (2) Androgen Insensitivity Syndrome (AIS); (3) Aphallia; (4) Clitoromegaly; (5) Congenital Adrenal Hyperplasia; (6) gonadal dysgenesis; (7) hypospadias; (8) Klinefelter Syndrome; (9) micropenis; (10) mosaicism involving "sex" chromosome; (11) Mayer-Rokitansky-Hauser-Syndrome (MRKH); (12) ovo-testes; (13) Partial Androgen Insensitivity Syndrome; (14) Progestin Induced Virilization; (15) Swyer Syndrome; and (16) Turner Syndrome.²⁷⁷

Though the medical community has identified some conditions producing intersexuality, there remains many diverse and complex difficulties ahead. With only recent recognition that sex is better identified on a spectrum and a lack of research in the area, all that can truly be said about a person with any of the sixteen conditions is that he or she does not have a typical reproductive or sexual autonomy.²⁷⁸ This makes the true identification of the individual exceedingly difficult when sex is overwhelmingly viewed to be a binary classification into male or female. While sex is better viewed on a spectrum, not all people who are intersex identify that way, some identify as men or women.²⁷⁹ Identifying as male or female but not having the

²⁷⁷ Intersex Conditions, INTERSEX SOCIETY OF NORTH AMERICA, http://www.isna.org/faq/conditions (last visited February 22, 2019).

²⁷⁸ Gandert et al., *supra* note 15.

²⁷⁹ Hila Viloria & Dana Zzyym, *How Intersex People Identify*, INTERSEX CAMPAIGN FOR EQUALITY (July 10, 2015), https://www.intersexequality.com/how-intersex-people-identify/.

reproduction or sexual autonomy to support that identification makes the inclusion of intersex athletes in elite sport competition very challenging.

Intersexuality is not very common, but in the small world of elite sports the representation can be meaningful. Overall, an estimated 1.7% of the population is intersex, making intersex about as common as having red hair.²⁸⁰ In regard to the sports arena, exercise physiologist and medical doctor Stéphane Bermon of the Monaco Institute of Sports Medicine alleges he has unpublished data qualifying that 0.71% of female athletes at the 2011 Daegu IAAF world championships were intersex.²⁸¹ The exact number of intersex athletes currently participating in Olympic and World competition is not reported, but the sexual testing of females, in particular, and regulations around the female classification makes the challenges presented widespread.

II. Sex Testing in Sports

a. The Early Years

The original purpose of sex testing in women's sports was not to *include* but to *exclude* athletes from participation. "The founder of the modern Olympic Games, Pierre de Coubertin,...was opposed to women's participation throughout his term as International Olympic Committee (IOC) President."²⁸² Pierre believed sport competition demonstrated personal worth and personal worth came from the social domination of others, which was an inappropriate goal

²⁸⁰ Hida, *How Common is Intersex? An Explanation of the Stats.*, INTERSEX CAMPAIGN FOR EQUALITY (Apr. 1, 2015), https://www.intersexequality.com/how-common-is-intersex-in-humans/.

 ²⁸¹ Richard A. Lovett, *Do intersex women athletes have an edge over the field?*, COSMOS (Aug. 16, 2016), https://cosmosmagazine.com/biology/do-intersex-women-athletes-have-an-edge-over-the-field.
 ²⁸² Gandert et al., *supra* note 15.

for women.²⁸³ From this belief came an exclusion of women from Olympic competition, reinforcing the overall poor and unequal treatment of women in society.

It was only after the women's movement and a strong initiative for women's inclusion that the issue was revisited. In 1928, female athletes finally gained the opportunity to compete in the Olympic Games, but their participation was limited to only track and field events.²⁸⁴ The inclusion of women came not from changed attitudes or social movement, but rather curtailed from necessity and a desire to compete at the Olympics with the Soviet Union and Eastern Bloc nations during the Cold War.²⁸⁵

As if hurdling the barrier to merely participate was not enough, the inclusion of female competition in the Olympic Games produced feelings of disregard for female emotional and mental health. These new opportunities led to a belief that female athletes were too masculine and unattractive, causing suspicion that some men were masquerading as females.²⁸⁶ With allegations increasing during both the 1936 Berlin Games and the 1960 Rome Olympic Games, the IOC and the IAAF began to establish sex verification procedures.²⁸⁷

In the late 1960s, the first sex verification measure was instituted for all female competitors.²⁸⁸ Early sex tests required female competitors to parade naked in front of a panel of judges for a physical inspection.²⁸⁹ These "nude parades" were exceptionally humiliating and

- ²⁸⁴ Id.
- ²⁸⁵ Id.
- ²⁸⁶ *Id.* at 401.
- ²⁸⁷ *Id.* at 402.

²⁸³ Id.

²⁸⁸ Gandert et al., *supra* note 2 at 402.

²⁸⁹ Id.

many female athletes rejected the implementation of the inspections.²⁹⁰ Strong criticisms and female backlash led to the adoption of a new test, the Barr body test, a sex chromatin test.²⁹¹

b. The Barr Body Test

In efforts to create a new, less humiliating test, the IOC introduced the Barr body test at the 1968 Mexico City Olympic Games.²⁹² The Barr body test was a "*sex chromatin test*", or "*buccal smear test*", involving a microscopic examination of cells scraped from the inner lining of a female athlete's check.²⁹³ Typically, in an athlete with the biological makeup of majority male, there will be one X chromosome and one Y chromosome, while the biological makeup of majority female is two X chromosomes.²⁹⁴ In females, the second X chromosome is "deactivated 'to form a Barr body in the nucleus of cells.'"²⁹⁵ Males will not have a second inactive X chromosome and therefore do not have any Barr bodies.²⁹⁶ The belief was if the Barr body test was negative, the individual had more than one X chromosome (a "female"), and if the test was negative, the individual tested positive, they would be eligible for competition; if they tested negative, they would be disqualified as not "female".²⁹⁸ Although the Barr body test was less intrusive and degrading, the test rested on the presumption that typical male and female chromosomes produced typical male or female sexual anatomy and physiology.

²⁹⁰ Josh Rakic, *Agony of the unfairer sex*, THE SYDNEY MORNING HERALD (Aug. 5, 2012), https://www.smh.com.au/sport/agony-of-the-unfairer-sex-20120804-23m90.html.

²⁹¹ Gandert et al., *supra* note 2 at 402.

²⁹² Id

²⁹³ Id.

²⁹⁴ Gandert et al., *supra* note 2 at 402.

²⁹⁵ *Id.* at 403.

²⁹⁶ Id.

²⁹⁷ Id.

²⁹⁸ Gandert et al., *supra* note 15 at 40; *see also* About the IIAF, *supra* note 2.

With an increased understanding of biology and chromosomal makeup, the Barr body test began to fall short of meeting the objectives. The biological and chromosomal makeup of intersex individuals challenged the presumptions the Barr test rests on. Illustrative of this are the many conditions discussed that produce intersexuality. For example, with Turner's syndrome, it is common for a person to be missing an entire chromosome.²⁹⁹ Somebody with Turner's syndrome could have the appearance of a female but lacking the second X chromosome, they will not have any Barr bodies.³⁰⁰ Here, difficulties arise since although not a typical female, the person does not have a Y chromosome and thus can't be classified as male either. Yet, the person in this scenario would be excluded from female competition in its entirety.

The Barr body test not only falsely excluded people, but falsely included them as well. With Klinefelter syndrome, the person does not have a Y chromosome and cannot be classified as a male either; the individual will appear to be a male, but will have an XXY karyotype.³⁰¹ This condition result in a person having a second X chromosome (and Barr bodies) and a Y chromosome; under the Barr body test, this individual would be admitted into female competition even though they are outwardly male.³⁰² Conditions like Turner's and Klinefelter's syndrome are only the beginning of the challenges raised by intersexuality. These difficulties ultimately led the IAAF to halt compulsory sex testing in 1991.³⁰³

c. Polymerase Chain Reaction and the End of Compulsory Sex Testing

As the IAAF ceased compulsory sex testing, the IOC continued to screen female participants in the Olympic Games.³⁰⁴ After the failure of the Barr body test, the IOC made its transition to a

²⁹⁹ Id

³⁰⁰ Gandert et al., *supra* note 15, at 403.

³⁰¹ Id.

³⁰² *Id.*

 $^{^{303}}$ Id.

³⁰⁴ Id.

Polymerase Chain Reaction (PCR) test.³⁰⁵ This test "detects the Sex-Determining Region Y (SRY) gene which is found on the male chromosome."³⁰⁶ The IOC made this switch since it was thought that the SRY gene was "necessary for the development of testicles in males."³⁰⁷ However, this later proved to be false as testicular development requires a combination of many different genes.³⁰⁸ Due to its short span of believed accuracy in the medical community, the PCR test was dispensed of quickly and was only used during the 1992 and 1996 Olympics.³⁰⁹

In 1999, the IOC ended compulsory sex testing, although federations like the IAAF still retain the authority to subject individual athletes to sex testing.³¹⁰ Current Chairman of the IOC Medical Commission, Arne Ljungqvist, has stated several reasons for the discontinuation, including that genetics tests will not fulfill the aims of gender verification in sport since there is no single and adequate laboratory method for screening for gender.³¹¹ As the complexities of sex have grown more evident, the IOC and IAAF have struggled to protect fairness in competition that is based on binary categories of male and female.

Even though the purpose of sex verification was centered around males masquerading as women, an actual man has never been detected. However, women who appear to be a little too masculine and a little less feminine have repeatedly been subject to prove their femininity.³¹²

III. Testosterone and its Relation to Performance Advantage

 309 Id.

³⁰⁵ *Id.* at 404.

³⁰⁶ *Id.* at 404-05.

³⁰⁷ *Id.* at 405. ³⁰⁸ *Id.*

³¹⁰ Id.

³¹¹ Gandert et al., *supra* note 15, at 405.

³¹² J. Michael Bostwick & Michael J. Joyner, *The Limits of Acceptable Biological Variation in Elite Athletes: Should Sex Ambiguity Be Treated Differently From Other Advantageous Genetic Traits?*, 87 MAYO CLINIC PROC. 509 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538474/pdf/main.pdf.

The alleged unfair athletic advantage that intersex athletes have over other athletes is the driving force behind regulations that prohibit intersex athletes from competition. To be discussed in detail later, the two regulations in reference are the IAAF's 2011 hyperandrogenism regulation and the 2018 female classification regulation. Since the 2011 regulation is caught up in the arbitration court and the 2018 regulation is in current implementation stages, attention will be paid to the statistical findings of the study used to promulgate the latter.

The key submission by the IAAF in promulgating the 2018 regulation was a study from 2017 published in the British Journal of Sports Medicine.³¹³ Many researchers have called into question the integrity of the data as the study's methodology falls short of adequate. Before discussing the study's shortcomings, it is imperative to discuss the study itself. Conducted by Stéphane Bermon and Pierre-Yves Garnier, the British study found that elite female track and field athletes with higher levels of testosterone had a 1.8 to 4.5 percent competitive advantage over women with lower testosterone levels.³¹⁴ Further, the study suggested this advantage is most profound in certain events: the 400m, 400m hurdles, 800m, hammer throw, and pole vault events.³¹⁵ The observations consisted of blood samples of male and female athletes competing at the 2011 and 2013 World Championships in Daegu and Moscow.³¹⁶

The study, however, is not without many pitfalls and limitations. First, the findings of the study operate on a confusion between correlation and causation. As a cardinal rule: Correlation does not imply causation. Correlation is a statistical technique which tells us how strongly the pair of variables are linearly related and change together. It does not tell us why and how, it only

³¹³ Stéphane Bermon & Pierre-Yves Garnier, Serum androgen levels and their relation to performance in track and field: mass spectrometry results from 2127 observations male and female elite athletes, 51 BRIT. J. OF SPORTS MED. 1309 (2017).

³¹⁴ Id. at 1314. ³¹⁵ Id.

³¹⁶ Id.

tells us that a relationship merely *exists*. Conversely, causation tells us that any change in the value of one variable will *cause* a change in the value of another variable, which means one makes the other happen. That being said, this study conflates the two and it proves to be a critical mistake in its interpretation.

Bermon and Garnier conclude that female athletes with higher levels of testosterone have a competitive advantage over females with normal levels of testosterone.³¹⁷ That is to say, the study is misinterpreted to suggest that there is a causal relationship between high testosterone levels and athletic performance. However, the authors tested for a *correlation* between the two, they did not control for factors that would allow them to conduct a causation model.³¹⁸ Supplanting one for another leads to faulty interpretations, like the one here, and is a sloppy statistical error. In fact, in Dutee Chand v. Athletics Federation of India (AFI) & The International Association of Athletics Federation (IAAF), a case to be discussed in further detail later, the Court of Arbitration for Sport noted its inability to differentiate the effect of nonnaturally and naturally-occurring testosterone in the body since "the correlation of naturallyoccurring testosterone to athletic performance did not prove causation."³¹⁹ Therefore, for the regulation to be valid, the IAAF had to prove that "increased testosterone significantly impacts athletic performance and provides a substantial competitive advantage."³²⁰ The IAAF was unable to do so.³²¹ The British Sports Medicine study does nothing to resolve this issue and instead continues to make the same error.

³¹⁷ Id.

³¹⁸ Andrew, *Publish your raw data and your speculations, then let other people do the analysis: track and field edition*, STAT. MODELING, CAUSAL INFERENCE, AND SOC. SCI. (Aug. 21, 2017),

https://statmodeling.stat.columbia.edu/2017/08/21/publish-raw-data-speculations-let-people-analysis-track-field-edition/.

³¹⁹ CAS 2014/A/3759 Dutee Chand v. Athletics Federation of India (AFI) & The International Association of Athletics Federation (IAAF).

³²⁰ *Id.* at 158.

³²¹ Id.

The British study makes another critical mistake by counting some observations twice. Specifically, more than one time is included for an individual across the two World Championships. For example, an athlete with "high" testosterone levels and a "fast" time in 2011 was again recorded in 2013. In the results, this makes it seem as though there are two individuals with high levels and "too fast" times when in actuality there is only one. This renders the data problematic since it misconstrues the field being surveyed. In fact, a reconstruction of the study suggests that between 17% and 33% of the values used are inaccurate.³²² For a highly selective model of this type, this is a huge error as there is a high possibility that nearly a third of the data is outright wrong.

Even assuming this is true, there remains the common belief that society actually *expects* elite athletes to be biologically more inclined to perform. Quite candidly, nobody wishes to watch those that are "normal". If this were not the case, then success in sports would come down to training and dedication, but we know much more fares into one's achievements. When studying elite female athletes at the World level, it would be more surprising to find their levels of testosterone are congruous with normal athletes than that they were not. This being so, there would virtually be no statistical significance to the study and no regulation to be had.

Taking all of these errors in totality, the IAAF's regulation is incomplete and inaccurate at best. The passage of an international regulation on such low standards of statistical scrutiny should be an embarrassment. Even if taken at face value, creating policy on such weak findings in light of critical errors is extremely insensible. The British study used in efforts to supplement

³²² Ross Tucker, *Letter to BJSM reinforcing call for retraction of IAAF research on testosterone in women*, THE SCI. OF SPORT (Aug. 2, 2018), https://sportsscientists.com/2018/08/letter-to-bjsm-reinforcing-call-for-retraction-of-iaaf-research-on-testosterone-in-women/.

the findings of Dutee Chand's case has failed miserably and it remains ambiguous whether high testosterone levels confer a significant competitive advantage.

IV. The History of Female Classification in Sports

In an effort to allegedly preserve fairness in competition, the IAAF has promulgated many regulations defining the female classification. Although the regulations may be of different title or language, the effect and purpose remain the same – to exclude female athletes who do not fit the classification of a typical female. Dating back to 1936, there has been a long-standing history of discrimination and exclusion of over-performing female athletes.³²³

Professional sports organizations have been troubled by the difficult issue of sex classification for decades. This practice was first implemented to reduce the number of males masquerading as females, but testing was never easy and often unreliable.³²⁴ The first athletes to grapple with sex verifications and classification regulations were Stella Walsh and Helen Stephens.³²⁵ At the "Hitler Olympics" in Berlin in 1936, Stella Walsh, second runner-up of the United States, accused winner Helen Stephens of being male.³²⁶ Stephens was forced to submit to a visual inspection of her internal genitalia, and passed. ³²⁷ Ironically enough, when Walsh was later killed in cross fire during a bank robbery, examination revealed that Walsh had ambiguous genitalia and abnormal sex chromosomes.³²⁸ A few years later, in the 1960s and at the start of robust and required visual sexual inspections, Ewa Klobukowka, medalist in two running events in 1964, became the first person to fail a compulsory sex test.³²⁹

³²³ Bostwick & Joyner, *supra* note 62 at 509.

³²⁴ Id.

³²⁵ Id.

³²⁶ Id. ³²⁷ Id

³²⁸ Bostwick & Joyner, *supra* note 62.

³²⁹ Id.

Between the 1984 and 1988 games, the number of female athletes being subjected to sex testing increased drastically.³³⁰ Sex inspections were forced upon female athletes both with and without speculation of their sexual ambiguity.³³¹ One of the most formidable females subjected to a sex inspection was a world-class Spanish runner, Maria Martinez Patino.³³² Patino failed the sex testing and "was found to have an unsuspected XY karyotype consistent with a previously undiagnosed complete androgen insensitivity syndrome."³³³ She refused to withdrawal or fake injury, as requested, and instead went on to win gold at the World Championships.³³⁴ Patino was subsequently stripped of her medal, kicked off her national team, and excluded from competition.³³⁵ Patino challenged her case and eventually became the first woman to be granted a reinstatement.³³⁶ Unfortunately, her reinstatement came a bit past her prime as she failed to qualify for the Olympics in her home country.³³⁷

Patino's case forced the IAAF to reconsider its stance on sex testing.³³⁸ Her case was illustrative of the fact that due to uncontrollable biological processes, all athletes (even at the highest level) have a very small window for elite competition.³³⁹ This makes the lengthy fight for eligibility perilous to their career because reinstatement generally comes after that small window. Despite having done nothing wrong and possessing no real advantage, female athletes subjected

³³⁰ Id.

³³¹ See id.

³³² Id.

³³³ Bostwick & Joyner, *supra* note 62.

³³⁴ Shawn M. Crincoli, You Can Only Race if You Can't Win? The Curious Cases of Oscar Pistorius & Caster Semenya, 12 TEX. REV. ENT. & SPORTS L. 133, 170 (2011).

³³⁵ *Id.* at 170-71.

³³⁶ Bostwick & Joyner, *supra* note 62.

³³⁷ Crincoli, *supra* note 84, at 171.

³³⁸ Id.

³³⁹ Id.

to this process lost their opportunity to compete.³⁴⁰ This is the ultimate price to pay when elite athletes have dedicated their entire lives to training and competition.

Due to the publicity of Patino's case, the IAAF ended compulsory-based testing, though reserving the right to test athletes based upon speculation and allegations.³⁴¹ The IOC continued its use.³⁴² In 2006, Santhi Soundarajan of India was forced to undergo a sex test after medaling at the Asian games.³⁴³ She failed and was subsequently told she was "insufficiently female to be competing among women."³⁴⁴ After the discovery of her intersexuality, Soundarajan attempted suicide.³⁴⁵ Fortunately, the attempt was unsuccessfully, and to date, she works with youth sports groups in an effort to reclaim her life.³⁴⁶

In 2008, an athlete by the name of Caster Semenya hit the World stage. Semenya is a middle-distance champion and world-class runner.³⁴⁷ At eighteen years old, Semenya won gold at the 2009 World Championships, shattering even her own personal records.³⁴⁸ Due to her performance and significant improvements, the IAAF investigated Semenya and subjected her to sex testing.³⁴⁹ During this time of investigation, Semenya was ineligible to compete.³⁵⁰ The IAAF never made it clear on what basis officials had decided to test her status as a woman rather than testing for performance enhancing drugs.³⁵¹ The IAAF cites her performance as reason, but this would mean the current World Record holder, and all those with times above Semenya's,

³⁴³ *Id.* ³⁴⁴ *Id.*

 346 *Id*.

³⁴⁹ Id.

³⁴⁰ See id.

³⁴¹ *Id.* at 171.

³⁴² Crincoli, *supra* note 84, at 171.

 $^{^{345}}$ *Id*.

³⁴⁷ *Id.* at 136.

³⁴⁸ Id.

³⁵⁰ Id. at 159.

³⁵¹ Gandert, *supra* note 15, at 377.

should also be subject to testing.³⁵² However, these other athletes were not tested proving that performance alone was not the reason for her testing.³⁵³

Since the only pieces of evidence present to officials were Semenya's performance and her physical appearance, this left her physical appearance the only possible cause for her testing.³⁵⁴ To IAAF officials, Semenya's appearance must have been outside the realm of what they believed to be the normal standard deviation of a female.³⁵⁵ Speculation of this nature runs the risk of discrimination against female athletes who do not exemplify traditional female stereotypes.³⁵⁶ Eleven months after the investigation and with much time and dignity wasted, the IAAF cleared Semenya to race.³⁵⁷ The report of intersexuality has neither been confirmed nor denied.³⁵⁸

In 2011, the IAAF became the first international sports federation to approve a regulation governing the eligibility of female athletes with hyperandrogenism.³⁵⁹ The regulation was based on a conclusion by an expert group and the IOC's medical commission.³⁶⁰ The conclusion was that female athletes with hyperandrogenism have a competitive advantage over other females such that the two should not compete together.³⁶¹

In order to compete under the 2011 regulation, a female must meet the requisite requirements. That is, "(i) She has androgen levels below the normal range; or (ii) She has

iaaf.

³⁵² *Id.* at 401.

³⁵³ Id.

³⁵⁴ See id.

³⁵⁵ Id.

³⁵⁶ *Id*.

³⁵⁷ Crincoli, *supra* note 84, at 157.

³⁵⁸ *Id.* at 137.

³⁵⁹ IAAF to Introduce Eligibility Rules for Females with Hyperandrogenism, IAAF (Apr. 12, 2011), https://www.iaaf.org/news/iaaf-news/iaaf-to-introduce-eligibility-rules-for-femal-1.

 ³⁶⁰ Press Ass'n, *IAAF approves new rules on hyperandrogenism*, THE GUARDIAN (Apr. 12, 2011, 7:43 AM), https://www.theguardian.com/sport/2011/apr/12/iaaf-athletics-rules-hyperandrogenism-caster-semenya.
 ³⁶¹ Darryl Hutcheon, *Hyperandrogenism in athletics: a review of Chand v. IAAF*, LAWINSPORT (Aug. 7, 2015), https://www.lawinsport.com/topics/sports/item/hyperandrogenism-in-athletics-a-review-of-chand-v-

androgen levels within the normal range but has an androgen resistance such that she derives no competitive advantage from having androgen levels in the normal male range."³⁶² If an athlete did not meet these requirements, she would be ineligible to compete or may be asked to submit to medical treatment to reduce testosterone levels.³⁶³ The key principles of the regulation primarily excluded females with hyperandrogenism.

The IAAF's regulation was in place from May 1, 2011 to July 24, 2015 when it was suspended by the Court of Arbitration for Sport ("CAS").³⁶⁴ In *Dutee Chand v. Athletics Federation of India (AFI) & The International Association of Athletics Federation (IAAF)*, Chand, a world-class Indian sprinter, challenged the regulation on grounds that it "unfairly discriminated against women who naturally produced higher levels of testosterone."³⁶⁵ The IAAF argued, to keep things fair, the regulation must be in place since females with hyperandrogenism have a competitive advantage over those who do not.³⁶⁶ Unsatisfied with the evidence the IAAF provided, the CAS suspended the regulations in July of 2015.³⁶⁷ The CAS gave the federation up to two years to provide evidence proving the "actual degree of performance advantage" due to hyperandrogenic females' higher testosterone levels.³⁶⁸ The court also noted that the hyperandrogenism regulations were "prima facie discriminatory because they applied only to female athletes and placed the burden on female athletes to get tested – a requirement not in place for males."³⁶⁹ For its named purpose of ensuring a fair playing field for

³⁶² Id.

³⁶³ Id.

³⁶⁴ See id.

³⁶⁵ Dutee Chand v. Athletics Fed'n of India (AFI) & amp; The Int'l Ass'n of Athletics Fed'n (IAAF), CAS

^{2014/}A/3759, Interim Arbitral Award, ¶ 4 (Ct. of Arb. for Sport July 24, 2015).

 $^{^{366}}$ *Id.* at ¶ 244.

 $^{^{367}}$ Id. at ¶ 547-48.

³⁶⁸ Id.

³⁶⁹ Id.

athletes, the court ordered the IAAF to establish the regulation was necessary, reasonable, and proportionate to their purpose.³⁷⁰

At the end of two years and after sufficient evidence failed to be submitted, the CAS gave the IAAF different instructions.³⁷¹ In a July 2017 statement, the CAS granted the IAAF an extension until September 2017 to file sufficient scientific evidence.³⁷² If the federation failed to do so, the regulation would be declared void.³⁷³ The IAAF also had a June 2018 deadline to advise the CAS as to how it intends to "implement its revised regulations and withdraw its original Hyperandrogenism Regulations."³⁷⁴

In April of 2018, the IAAF issued its new requirements.³⁷⁵ The regulation, titled Eligibility Regulations for the Female Classification (Athletes with Differences of Sex Development), hereinafter referred to as "Regulation", was set to go into effect November 1, 2018.³⁷⁶ Since the court mandated the IAAF ground their revisions in quantitative scientific evidence to support the relationship, the IAAF commissioned the British Sports Medical Journal study.³⁷⁷ As discussed previously, this study contained critical statistical mistakes and inappropriate inferences, nevertheless, the IAAF issued the rule.

The new Regulation, which is up for consideration in the CAS currently, contains new language, but the IAAF has stuck with its same goal. The Regulation seeks to exclude from competition in certain events, women who cannot meet the specific criteria.³⁷⁸ Using the troubled

 377 IAAF, supra note 5.

³⁷⁰ Chand, CAS 2014/A/3759 at ¶ 4.

 ³⁷¹ Andy Brown, *CAS grants IAAF another extension in Dutee Chand case*, SPORTS INTEGRITY INITIATIVE (Jan. 19, 2018), https://www.sportsintegrityinitiative.com/cas-grants-iaaf-another-extension-dutee-chand-case/.
 ³⁷² Id.

³⁷³ Id.

³⁷⁴ Id.

 ³⁷⁵ IAAF Introduces New Eligibility Regulations for Female Classification, IAAF (Apr. 26, 2018), https://www.iaaf.org/news/press-release/eligibility-regulations-for-female-classifica.
 ³⁷⁶ IAAF, supra note 3.

³⁷⁷ *Id.*

³⁷⁸ Id.

findings of the British Sports Medical Journal, the restricted events are distances between 400m to one mile, applying to female athletes with DSD.³⁷⁹ These events are where the IAAF believes the most performance-enhancing benefits can be obtained from elevated levels of circulating testosterone.³⁸⁰

Much like the original regulation, the new regulation still places heavy restrictions on those female athletes who do not meet the typical definition of a "female". Athletes with circulating testosterone levels above 5 nmol/L are considered to have a DSD, for all intents and purposes of the Regulation.³⁸¹ If a female athlete with DSD wishes to compete in one of the restricted events at International Competition, she must meet the following conditions: "(a) she must be recognized by law either as female or as intersex (or equivalent); (b) she must reduce her blood testosterone level to below five (5) nmol/L for a continuous period of at least six months (e.g. by use of hormonal contraceptives); and (c) thereafter she must maintain her blood testosterone level below five (5) nmol/L continuously (i.e.: whether she is in competition or out of competition) for so long as she wishes to remain eligible."³⁸² In short, the 2018 Regulation is much more strict and imposes harsh requirements on female athletes in order to gain reinstatement and/or continue to compete.

Without an overwhelming reason for exclusion, it is difficult to justify a regulation with such great implications. In its Explanatory Notes to the Regulation, the federation grounds the Regulation in notions of fairness and maintaining meaningful competition.³⁸³ The IAAF additionally recognizes that sex is a biological umbrella and makes mention of those who fall

³⁷⁹ IAAF, *supra* note 7.

³⁸⁰ Id.

³⁸¹ Id.

 $^{^{382}}$ IAAF, *supra* note 3.

³⁸³ IAAF, *supra* note 7.
under neither category and instead are intersex, known to have DSD.³⁸⁴ Nevertheless, the purposes are contrary to the community's sensitivities and basic understandings.

In part due to its importance in analysis and also its absurdity, some important portions of the IAAF's alleged purpose for the Regulation will be produced in full below, while others are summarized. The IAAF states:

"To ensure fair and meaningful competition in the sport of athletes, competition has to be organized within categories that create a level playing field and ensure that success is determined by talent, dedication, hard work, and the other values and characteristics that the sport embodies and celebrates. In particular: The IAAF wants athletes to be incentivized to make the huge commitment and sacrifice to excel in the sport, and so to inspire new generations to join the sport and aspire to the same excellence. It does not want to risk discouraging those aspirations by having unfair competition conditions that deny athletes a fair opportunity to succeed."³⁸⁵

The IAAF continues on to acknowledge its respect for all individuals, "including individuals with DSD", as if they were separate in the first place.³⁸⁶ Ironically enough, the IAAF proposes the Regulation is designed to protect female athletes with DSDs, not exclude them.³⁸⁷ However, in Section VI there exists analysis on how this Regulation's purpose runs contrary to the essential core rules and regulations governing sport organizations like the IAAF. For now, it is enough to say these purposes are suspicious and hazy at best.

V. World Anti-Doping Agency and the Code

³⁸⁷ Id.

³⁸⁴ Id.

³⁸⁵ Id.

³⁸⁶ Id.

The World Anti-Doping Agency, (WADA), has tremendous influence and scope. The World Anti-Doping Code, hereinafter referred to as the "Code", is the core document issued by WADA and intended to harmonize regulations regarding anti-doping in sport across all sports and all countries.³⁸⁸ To the Code are signatories which include national anti-doping organizations and international federations.³⁸⁹ The IAAF is signatory to the Code.³⁹⁰ All signatories must adhere to the Code.³⁹¹ That is, all signatories "shall implement applicable Code provisions through policies, statutes, rules or regulations according to their authority and within their relevant spheres of responsibility."³⁹² Thus, the Code provides the framework at which policies, rules, and regulations for sport organizations must adhere.³⁹³

To better understand the goals of WADA, it is important to look towards the Code's intents and purposes. The three ideals used by WADA are: "fairness ("leveling the playing field"), protecting the health of the athlete, and maintaining the "spirit of sport".³⁹⁴ As a signatory, alignment with the ideals of WADA and purposes of the Code is a crucial starting point for analyzing the completeness of a federation's rule or regulation. Hence, the legitimacy of an international regulation is crucial in assessing the proportionality of the means adopted to pursue the aim.³⁹⁵ If an international federation's promulgated regulation cannot gain compliance with the Code, as a signatory, the federation should be considered outside of compliance.

³⁸⁸ World Anti-Doping Code, WADA, https://www.wada-ama.org/en/questions-answers/world-anti-doping-code (last visited February 17, 2019).

³⁸⁹ Id.

³⁹⁰ Code Signatories, WADA, https://www.wada-ama.org/en/what-we-do/the-code/code-signatories (last visited February 17, 2019).

³⁹¹ WADA, *supra* note 138.

³⁹² *Id*.

³⁹³ Id.

³⁹⁴ Hard, *supra* note 9, at 535.

³⁹⁵ Id.

At the outset one may wonder how a regulation designed to prohibit female athletes with DSD from competition in certain restricted events can run afoul a document published to prohibit the use of certain performance-enhancing drugs. Arguments can be made that these two do not cross paths since female athletes with DSDs are not being asked to *use* performance-enhancing drugs, a clear violation of the Code, but instead, are being asked to use drugs to *reduce* their natural performance-enhancing biological processes. In that limited regard the argument is fair. However, being that the Code is a governing document for all signatories, an international federation cannot promulgate a regulation that runs contrary to the very spirit of the Code and purpose of WADA.

It may help to illustrate this idea in a more simple, understandable manner. For example, the federal government operates on the backbone of the U.S. Constitution. This backbone includes a presumption of innocence until proven guilty, free trade, and free speech. To the U.S. Constitution are signatories, the states, who must adhere to each provision therein found. If a state wishes to promulgate a rule that runs contrary to the Constitution, the state action will be challenged on grounds the proposal runs afoul the Constitution. A proponent may also allege other arguments, such as a policy rationale, feasibility, precedent, and/or implications of its passage. If a state law is found to run afoul the federal Constitution, the state rule shall not pass.

This state rule, falling subservient to the federal directive, is very similar to the issue at hand. WADA, for purposes of this illustration, is the federal government. WADA has published the Code, which operates on the backbone of WADA's three ideals – fairness, protecting the health of the athlete, and maintaining the spirit of sport. The international federations are signatories to the Code and must follow the rules and regulations found within. If an international federation wishes to pass a regulation, they must be in adherence with the Code.

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That is, the regulation cannot run contrary to the overarching ideals. A challenger may argue the regulation, in fact, does not protect the health of the athlete, or has negative implications such that the means and ends are disproportionate. If the regulation is found to run contrary to these basic ideals, the regulation should be deemed void.

VI. Classification Regulation Violates Governing Principles

Using broad assertions of "fairness," "health," and "spirit of sport" to justify its directives, WADA's founding principles have made it difficult to accept the IAAF's Regulation as valid. In particular, this section will discuss the problematic approach to binary classifications in sports, an analysis of how the Regulation runs contrary to the three ideals of WADA, and a discussion into the relevant but less glaring arguments discrediting the Regulation.

a. Problematic System of Binary Classification

The initial issue with the Regulation is that it assumes a binary model is most appropriate in sport competition. This notion rests in history as sports have always embraced the male or female system of sex. With increased understandings of sex, the binary model has since become oversimplified and outdated. The historic role of sex in sports relies on constructs of culture rather than science, which has proven people can have a variation of different chromosomal makeups outside of those that yield male or female.³⁹⁶ Therefore, sex is better understood on a spectrum which allows for individuals who are intersex to more appropriately identify.

Since the male-female dichotomy is a social construct and actually more than two sexes exist in nature, the system should be changed. Instead of asking how to fit in "exceptions", as the IAAF's Regulation seems to do, the IAAF and the IOC should break the habit of binary

³⁹⁶ Catherine Lee, *The Binary World of Sports*, THE NAT'L LAW REV. (June. 26, 2017), https://www.natlawreview.com/article/binary-world-sports.

thinking.³⁹⁷ At minimum, there should be a shift away from using a singular marker to determine sex for purposes of competition.³⁹⁸ Only after a change in the mindset of sport politics can serious consideration be given to ways in which the binary divide can be dissolved.³⁹⁹ The IAAF has recognized the advancements in the understanding of sex and indeed grounds the Regulation in this new understanding, but they have not yet moved away from the problematic habit of thinking.⁴⁰⁰

b. Regulation Runs Contrary to Three Ideals

In retaining its binary model, the IAAF's has issued a regulation that runs contrary to the principles of WADA's three ideals. First, an argument can be made that the playing field in sports can never *truly* be equal. If this is assumed, then the Regulation's purpose of preserving fairness in competition is undermined. Second, the Regulation calls for intersex female athletes to undergo hormone therapy and/or suggested medical procedures that are unsafe for the health of the athlete.⁴⁰¹ Third, the Regulation does little to maintain the spirit of sport since it reinforces dominant gender and sex stereotypes.

i. Fairness ("leveling the playing field")

The beauty of sports stems from its ability to demonstrate the universality of the human condition. Before discussing whether the Regulation preserves efforts to ensure a level playing field, it must be asked whether it is truly ever possible to have a level playing field. And even before that, we must ask "do we even *want* the playing field to be equal?" After all, it is the innate performance inequality of sports that makes the games entertaining.

³⁹⁷ Luke Schut, Deconstructing the Sex/Gender-Segregated Sports World (Jan. 22, 2018) (unpublished B.A. thesis, Ultrecht University) (on file with Ultrecht University Repository).

³⁹⁸ *Id.*

³⁹⁹ Id.

⁴⁰⁰ See IAAF, supra note 7.

⁴⁰¹ See *id*.

Sometimes, these inequalities can be of biological processes. Under the Regulation, intersex athletes like Caster Semenya are relegated to the sideline, but other athletes who possess a biological advantage are able to compete. For example, Michael Phelps, gold medalist swimmer and World Record holder, has disproportionately long arms and overly lax joints that allow him to swim at greater speeds than other competitors; Kevin Garnett, gold medalist basketball player, has agility, speed, and jumping ability that seems incongruous with his very tall height. ⁴⁰² Yet, these athletes are not forbidden from competition due to competitive advantages given to them at birth. Why was cyclist Lance Armstrong not excluded from competition due to his preternaturally high maximum oxygen consumption and overly-efficient oxygen use?⁴⁰³

This begs the question: why do we exclude some biological advantages but not others? To even suggest excluding athletes due to an advantage of no manipulation of their own sounds absurd. Yet the IAAF has done so with regulations that exclude athletes like Semenya. To no fault of her own, Semenya was born with a chromosomal makeup that allows her an alleged advantage over other female athletes.⁴⁰⁴ Assuming this advantage is statistically significant, which is at serious issue, there exists little to no difference between Caster Semenya and Lance Armstrong, yet Semenya is excluded while Armstrong is not. In its application this is a discriminatory Regulation because it singles out a class of individuals with the intent to level the playing field. If this alleged purpose is true, then other athletes with a naturally occurring

⁴⁰² Bostwick and Joyner, *supra* note 62.

⁴⁰³ Id.

⁴⁰⁴ Dean Eastmond, *Caster Semenya's problem isn't that she's intersex – it's that her femininity doesn't look how we want it to*, INDEPENDENT (Aug. 22, 2016), https://www.independent.co.uk/voices/caster-semenya-rio-2016-gold-800m-intersex-gender-femininity-doesnt-look-the-way-we-want-a7203506.html.

competitive advantage should also be excluded, but this is not the case under this Regulation. Henceforth, there must be other intents and purposes of the IAAF at play.

Aside from these naturally occurring biological processes that make the fairness of sports unfeasible, there are also other inequalities at play. There are different types of inequalities, such as that of natural endowments, and that of opportunity.⁴⁰⁵ For instance, athletes at the Oregon Project have access to multi-million-dollar technologies that enhance their performance considerably.⁴⁰⁶ Likewise, wealthier countries perform better at the Olympics because people have greater access to swimming pools, and gymnastic and track facilities.⁴⁰⁷ Countries with fewer resources have no such opportunities. These inequalities are of no less significance than natural endowments. In regard to leveling the playing field, wealthy countries and poor countries are allowed to compete side by side. Since restrictive regulations are not placed on those who come from countries with greater opportunity, the Regulation excluding those with natural endowments cannot stand. In fact, it is in overcoming these inequalities that sport finds its dramatic appeal.

Lastly, it must be seriously considered whether we even want a level playing field. To exclude only some athletes opens the door for issues of discrimination, but to exclude all athletes may eliminate too great a class. Since genetic variances and other inequalities in opportunity differentiate elite athletes from the average population and are what allow them to succeed in the first place, it makes little sense to argue the Regulation is leveling the playing field. Sports are an inherently unequal endeavor and should embrace and celebrate individuals who are able to entertain due to biological advantages, not disqualify them.

⁴⁰⁵ Hard, *supra* note 9, at 547-48.

⁴⁰⁶ Id.

⁴⁰⁷ Id.

ii. Protecting the health of the athlete

According to the IAAF's Regulation, if an intersex female athlete wishes to compete among other females, she must self-medicate for so long as she wishes to compete in certain restricted events.⁴⁰⁸ Specifically, the Regulation requires an intersex female athlete to: "reduce her blood testosterone level to below five (5) nmol/L for a continuous period of at least six months (e.g. by use of hormonal contraceptives; and thereafter she must maintain her blood testosterone level below five (5) nmol/L continuously (i.e. whether she is in competition or out of competition) for so long as she wishes to maintain eligibility to compete in the female classification in Restricted Events."⁴⁰⁹

WADA premises the regulations of international federations on satisfactory compliance of protecting the health of the athlete, but this requirement fails to meet that directive. In particular, the requirements are harmful to the female body and ask women to self-medicate in a space where little is known about the side effects or long-term consequences.⁴¹⁰ What is known, however, is these hormonal contraceptives indeed alter performance levels so greatly that they render the athlete essentially unable to compete.⁴¹¹ When the IAAF issued its hyperandrogenism regulation in 2011, Semenya was forced to comply by taking a daily medication to reduce her naturally occurring testosterone levels.⁴¹² This had a significant impact on Semenya's performance. In fact, after winning years before, Semenya lost at the 2011 World Championships

⁴⁰⁸ IAAF, *supra* note 3.

⁴⁰⁹ Id.

⁴¹⁰ Matt Lawton, *New IAAF rule will force Semenya to take medication or switch events*, IOL (Apr. 25, 2018), https://www.iol.co.za/sport/athletics/new-iaaf-rule-will-force-semenya-to-take-medication-or-switch-events-14637997.

⁴¹¹ *Id*.

⁴¹² Matt Lawton, *IAAF issues shocking new ultimatum to controversial Olympic star Caster Semenya*, NZHERALD, https://www.nzherald.co.nz/sport/news/article.cfm?c_id=4&objectid=12039149 (last visited February 17, 2018).

and the 2012 Olympics to Mariya Savinova.⁴¹³ It was only after Savinova was found using performance-enhancing drugs that Semenya was upgraded to gold in both events – the irony.⁴¹⁴

Aside from stripping female athletes of their accomplishments and penalizing them for natural occurrences outside of their control, the IAAF's medicinal requirement is detrimental to the athlete's health and wellbeing. After the Regulation's passage, a Yale University professor raised concerns about the potential health risks of medically reducing testosterone levels.⁴¹⁵ Katrina Karkazis stated, "Lowering testosterone can have serious life-long health effects. If done via surgery, women are at a high risk for osteoporosis."⁴¹⁶ With little known about the implications, the IAAF should take different routes to achieve their ends before backhandedly justifying its efforts in the name of protection for health.

Aside from an undiscovered world of side-effects, the medical reduction of testosterone is likely to be of no success. As mentioned previously, there is inconclusive evidence to support the IAAF's argument that increased levels of testosterone in intersex female athletes result in an unfair competitive advantage. That being said, the medical reduction of testosterone does nothing but require an athlete to self-medicate daily in the name of bad science. Adding to the discussion, Karkazis noted it is completely wrong to compare naturally occurring testosterone to testosterone doping.⁴¹⁷ In addition, Gideon Meyerowitz-Katz, a chronic disease epidemiologist in Australia, wrote: "Semenya's athleticism was attributed to a single molecule – testosterone – as though it alone earned her the gold, undermining at once her skill, preparation, and achievement."⁴¹⁸ In targeting only testosterone with its medication, the IAAF fails to account for other molecular

⁴¹⁵ Id.

⁴¹³ *Id*.

⁴¹⁴ Id.

⁴¹⁶ Id.

⁴¹⁷ Lawton, *supra* note 157.

⁴¹⁸ Id.

advantages and the commonplace notion that hard work yields great success. Further, in this regard, the IAAF comparing naturally occurring testosterone levels to those achieved by doping is inappropriate and misleading. Naturally occurring testosterone is not a banned substance. This renders any justification under the Code invariably wrong.

iii. Maintaining the "spirit of sport"

Having failed the prior two requisites for regulation, the IAAF further cannot satisfy WADA's ideal to maintain the "spirit of sport". WADA pulls from the Olympic Charter to delineate the spirit of sport: "Ethics, fair play and honesty, health, excellence in performance, character and education, fun and joy, teamwork, dedication and commitment, respect for rules and laws, respect for self and other participants, courage, and community and solidarity."⁴¹⁹ In its basic form, the Regulation habitually violates the spirit of sport. Since the Regulation is discriminatory, it necessarily contravenes every delineation from the agency. By creating a regulation that excludes some female athletes and not others the IAAF is dismantling, not protecting, the spirit of the sport. Further, the IAAF is reinforcing dominant gender and sex stereotypes by excluding those who do not neatly fit into the binary dichotomy or normative ideas about femininity. This includes her appearance, gender expression, and sexuality. No woman should be required to change her body to compete in women's sports. Such discrimination undermines the spirit of sport and violates WADA and the Olympic Charter.

Conclusion

The practice of sport is a human right, but the Regulation takes this right away from some and not others. As variations unfold and inclusivity expands, no one class should be held subservient to another or less "female". Like all athletes, what is at stake is far more than the

⁴¹⁹ Hard, *supra* note 9.

right to participate in sports. Women's bodies, their wellbeing, their ability to earn a livelihood, their identity, their privacy and sense of safety and belonging, are at great risk. Women's sports should be an inclusive endeavor, where women and gender nonconforming athletes across the physical and socioeconomic spectrum can compete on elite levels using the bodies they were born with. And in generality, the world of sport should welcome and empower all as the world changes.

<u>Re-Evaluating the Regulation of Executions</u>

Erin Kelly⁴²⁰

Abstract

The majority of states in the United States of America allow the death penalty to be a possible punishment for individuals convicted of certain crimes. The methods that states use to execute condemned prisoners has changed significantly over time, and each method has posed its own challenges in complying with the Eighth Amendment's protection against cruel and unusual punishment. This note discusses the evolution of the methods of execution in America, focusing on how case law, statutes, and policies have led to the current methods of various lethal injection protocols.

Lethal injection is now the standard method of execution in the US, and it has proven to be problematic. This note addresses the issues that the current methods of execution pose, arguing that the use of certain drugs in legal injections, such as midazolam, is a violation of the Eighth Amendment's prohibition of cruel and unusual punishment. This note also argues that inordinate delay in carrying out executions is also a form of unconstitutional punishment. This note concludes by recommending a solution to the current problems of frequently botched executions, difficulties in carrying out executions, and the psychological trauma condemned prisoners experience. The solution posed aims to restructure the responsibilities between states, the Supreme Court, and Congress, suggesting the issues faced on a national level should be addressed by the federal legislature.

Introduction

⁴²⁰ Syracuse University College of Law, Juris Doctor expected 2020. Thank you to my wonderful mother for continuously supporting me emotionally, financially, and physically throughout my academic, professional, and personal journeys.

Ronald Bert Smith, Jr., a former Eagle Scout and Army reservist, was executed on December 8, 2016 for his 1994 murder conviction.⁴²¹ At the beginning of his execution, Smith repeatedly heaved and coughed, clenched his fists, and raised his head.⁴²² There was continued movement throughout one of his arms during the execution, until he was finally pronounced dead after thirty minutes.⁴²³ Smith had previously filed a complaint challenging Alabama's method of execution as cruel and unusual under the Eighth Amendment.⁴²⁴

Smith challenged the method of execution because the state planned to use the drug midazolam as a part of the lethal injection protocol.⁴²⁵ The protocol consisted of a dose of midazolam, followed by rocuronium bromide, and then potassium chloride.⁴²⁶ Alabama previously used sodium thiopental as the first drug in the sequence, however, it became unavailable in 2011, and Alabama replaced it with pentobarbital.⁴²⁷ Pentobarbital became unavailable in 2014, which led the state to use midazolam as the first drug in its lethal injection protocol.⁴²⁸ States throughout the country faced the same drug shortage issues, causing each to alter its method of execution to

⁴²³ Id.

⁴²⁷ Id.

⁴²⁸ Id.

⁴²¹ Michael L. Radelet, *Botched Executions*, DEATH PENALTY INFO. CTR. (Mar. 1, 2018), https://deathpenaltyinfo.org/executions/botched-executions.

⁴²² Alabama Executes Killer Ronald Bert Smith Jr. After Two Temporary Supreme Court Holds, CNN NEWS (Dec. 9, 2016), https://www.cbsnews.com/news/alabama-executes-killer-ronald-bert-smith-jr-after-two-temporary-supreme-court-holds/ [hereinafter Ronald Bert Smith Jr.].

⁴²⁴ Grayson v. Warden, 672 F. App'x 956, 958 (11th Cir. 2016).

⁴²⁵ *Ronald Bert Smith Jr., supra* note 3.

⁴²⁶ Grayson, 672 Fed. Appx. at 959.

allow for the use of different, more controversial drugs.⁴²⁹ Many prisoners fought before, after, and alongside Smith to challenge the use of these new drugs, as they were not proven to be effective at rendering prisoners unconscious and unresponsive to pain.⁴³⁰ The methods of execution that states are currently using need to be re-evaluated and regulated on a national level.

I. Methods of Execution

Standard practices for methods of execution have changed over time. In the 19th century, hanging was the nationally accepted method, with forty-eight states implementing the practice.⁴³¹ Although only two states still allow for execution by hanging,⁴³² it is the method that has legally executed the largest number of people throughout the history of the United States.⁴³³

During his tenure, New York state governor David Hill appointed a commission of experts to identify the best possible method of execution.⁴³⁴ After a year of research, the commission determined that electrocution would be the most humane method.⁴³⁵ Accordingly, in 1888, New

⁴³² Elizabeth Davis & Tracy L. Snell, *Capital Punishment, 2016*, U.S. DEP'T JUST. at 11 (Apr. 2018), https://www.bjs.gov/content/pub/pdf/cp16sb.pdf; *State v. Gregory*, 427 P.3d 621, 622 (Wash. 2018).

⁴³³ Chris Wilson, *Every Execution in U.S. History in a Single Chart*, TIME, http://time.com/82375/every-execution-in-u-s-history-in-a-single-chart/ (last updated April 25, 2017).

⁴²⁹ Nathaniel A. W. Crider, Article, *What You Don't Know Will Kill You: A First Amendment Challenge to Lethal Injection Secrecy*, 48 COLUM. J.L. & SOC. PROBS. 1, 3-5 (2014).

⁴³⁰ Brief of Sixteen Professors of Pharmacology as Amici Curiae in Support of Neither Party at 8, *Glossip v. Gross*, 135 S. Ct. 2726 (2015) (No. 14-7955), 2015 WL 1247193.

⁴³¹ Baze v. Rees, 553 U.S. 35, 41-42 (2008).

⁴³⁴ Lane Florsheim, *The Evolution of the Death Penalty in One Map*, NEW REPUBLIC (Mar. 23, 2014), https://newrepublic.com/article/117114/death-penalty-evolution-map-how-executions-have-changed-states (stating that in 1889, the governor of New York appointed a commission of experts to find a humane method of execution); *Governor David Bennett Hill*, NAT'L GOVERNORS ASS'N (2015), https://www.nga.org/governor/david-bennett-hill/ (stating that David Hill was the governor of New York from 1885 to 1892).

⁴³⁵ Florsheim, *supra* note 15.

York was the first state to enact legislation to require electrocution as the primary method of execution, and other states eventually followed suit.⁴³⁶

After America entered World War I in 1917, the nation's armed forces faced Germany's chemical warfare.⁴³⁷ Within months, the US developed a wide variety of sophisticated chemicalbased weapons as well, which it used in combat against the Central Powers.⁴³⁸ After the war ended, researchers and developers that created these deadly chemical combinations sought continued and different uses of their work.⁴³⁹ This led Nevada to pass the Humane Execution Bill in 1921, making it the first state to implement execution by a gas chamber.⁴⁴⁰ However, like every method before it, states abandoned the practice in search of more humane methods. Now, three states still allow for execution by gas chamber.⁴⁴¹

In searching for alternative methods of execution, some states authorized the use of firing squads,⁴⁴² though this method is now only allowed in two states.⁴⁴³ In 1977, Oklahoma legislatures were the first to enable execution by lethal injection.⁴⁴⁴ Now, lethal injection is the standard method of execution in the United States, as it is authorized by thirty-three states.⁴⁴⁵ Due to

⁴³⁹ *Id.* at 56.

⁴⁴⁰ *Id.* at 63.

⁴³⁶ *Baze*, 553 U.S. at 42.

⁴³⁷ Scott Christianson, The Last Gasp: The Rise and Fall of the American Gas Chamber 42 (U.C. Press 2010).

⁴³⁸ *Id.* at 43-45.

⁴⁴¹ Davis & Snell, *supra* note 13, at 11-12.

⁴⁴² Baze v. Rees, 553 U.S. 35, 42 (2008).

⁴⁴³ Davis & Snell, *supra* note 13, at 11.

⁴⁴⁴ *Baze*, 553 U.S. at 42.

⁴⁴⁵ Davis & Snell, *supra* note 13, at 11; See State v. Gregory, 192 Wn.2d 1, 5 (Wash. 2018).

continued issues with lethal injections, two states have recently authorized execution by nitrogen hypoxia.⁴⁴⁶ However, this method has never been carried out before.⁴⁴⁷

a. Botched Executions

Even with these ever-changing practices, the Supreme Court has never ruled a method of execution to be unconstitutional.⁴⁴⁸ However, there is a long history of botched executions with almost every type of execution method.⁴⁴⁹ Botched executions are defined as those involving unanticipated problems, causing unnecessary agony for the prisoner, and reflecting gross incompetence of the executioner.⁴⁵⁰ Examples of botched executions that have occurred include inmates catching fire while being electrocuted, strangled during hangings, and being administered the wrong doses of drugs for lethal injections.⁴⁵¹

Arguably, the most alarming botched executions are the ones which are caused by the drugs that states are still using for executions today. In 2014, Clayton Lockett was executed using the drug midazolam as a part of the lethal injection chemical concoction.⁴⁵² Ten minutes after midazolam was administered, a prison official instructed the technician to check if Lockett was

⁴⁵⁰ *Id.* at 5.

⁴⁵¹ *Id.* at 6.

⁴⁴⁶ See Okla. Stat. tit. 22, § 1014(B); Miss. Code Ann. § 99-19-51(2).

⁴⁴⁷ Denise Grady & Jan Hoffman, *States Turn to an Unproven Method of Execution: Nitrogen Gas*, N.Y. TIMES (May 7, 2018), https://www.nytimes.com/2018/05/07/health/death-penalty-nitrogen-executions.html.

⁴⁴⁸ Baze, 553 U.S. at 48.

⁴⁴⁹ AUSTIN SARAT, GRUESOME SPECTACLES: BOTCHED EXECUTIONS AND AMERICA'S DEATH PENALTY 6 (2014).

⁴⁵² Julia Eaton, Note, "Warning: Use May Result in Cruel and Unusual Punishment": How Administrative Law and Adequate Warning Labels Can Bring About the Demise of Lethal Injection, 59 B.C.L. REV. 355, 356 (2018).

unconscious.⁴⁵³ Lockett responded by saying, "I'm not," which the technician confirmed.⁴⁵⁴ Lockett was later declared unconscious and the rest of the drugs were administered.⁴⁵⁵ However, Lockett was observed blinking, licking his lips, and then seizing.⁴⁵⁶ He was thrashing against his restraints and mumbling, with a pained expression on his face.⁴⁵⁷ Other botched executions attributable to the use of midazolam include that of Dennis McGuire, Joseph Wood, Ronald Smith, and Kenneth Williams.⁴⁵⁸

b. *Baze* and *Glossip*

In 2008, the United States Supreme Court held that in order to succeed on a claim that a method of execution is cruel under the Eighth Amendment, a condemned prisoner must establish that there is "a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm'" posed by the current method of execution.⁴⁵⁹ The Court further stated that "a condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative."⁴⁶⁰ However, if a prisoner is able to prove an alternative method of execution would be "feasible, readily implemented, and in fact significantly reduce a substantial risk of

⁴⁶⁰ *Id.* at 51

⁴⁵³ Paige Williams, *Witnesses to a Botched Execution*, NEW YORKER (Apr. 30, 2014), https://www.newyorker.com/news/news-desk/witnesses-to-a-botched-execution.

⁴⁵⁴ Id.

⁴⁵⁵ Eaton, *supra* note 33.

⁴⁵⁶ Williams, *supra* note 34.

⁴⁵⁷ Eaton, *supra* note 33.

⁴⁵⁸ Radelet, *supra* note 2; Jason Hanna, *Executed Inmate's Convulsions Put New Spotlight on Midazolam*, CNN (Apr. 28, 2017), https://www.cnn.com/2017/04/28/us/arkansas-execution-kenneth-williams-midazolam-convulsions/index.html.

⁴⁵⁹ Baze v. Rees, 553 U.S. 35, 50 (2008) (quoting Farmer v. Brennan, 511 U.S. 825, 842, 846 (1994)).

severe pain," then "a State's refusal to change its method can be viewed as 'cruel and unusual' under the Eighth Amendment."⁴⁶¹ Therefore, if a prisoner could prove either that a current method of execution was cruel and unusual under the Eighth Amendment, or if the prisoner could prove that another readily available method of execution would substantially decrease the risk of severe pain, then the prisoner could prevent being executed in an unconstitutional manner.

In *Glossip v. Gross*, the Supreme Court misinterpreted the holding of *Baze v. Rees*.⁴⁶² The Court combined the two alternative options a condemned prisoner had in order to prove a method of execution unconstitutional, thereby creating one insurmountable standard.⁴⁶³ With this new standard, a prisoner must prove that the method of execution creates a substantial risk of serious harm and that there is a feasible and readily implemented alternative procedure that would significantly reduce a substantial risk of serious harm.⁴⁶⁴ Lower courts applying the ruling of *Glossip v. Gross* have held that prisoners must satisfy both of these requirements in order to succeed on a claim that a method of execution is unconstitutional.⁴⁶⁵ If a court first rules on the question of whether the prisoner has proved an available alternative method, then it does not decide the issue of whether the current method is unconstitutionally cruel and unusual. Therefore, states can use unconstitutional methods as long as the prisoner cannot prove that there is an available alternative. This circumvents the important issue of whether or not prisoners are being executed in a manner that is in compliance with constitutional standards. This problem is further exacerbated

⁴⁶¹ *Id.* at 52.

⁴⁶² Glossip v. Gross, 135 S. Ct. 2726, 2794-95 (2015) (Sotomayor, J., dissenting).

⁴⁶³ *Id.*

⁴⁶⁴ *Id.* at 2737.

⁴⁶⁵ Abdur'Rahman v. Parker, 558 S.W.3d 606, 616-17 (Tenn. 2018); Price v. Comm'r, Ala. Dep't of Corr., 752 F. App'x 701, 704-05 (11th Cir. 2018).

by many courts' interpretation of a feasible and readily implemented alternative procedure and by the growing number of secrecy statutes.

c. Aftermath of *Baze* and *Glossip*

Some courts have interpreted the readily available alternative standard to mean that there is another method authorized by state statute.⁴⁶⁶ In a dissenting opinion, Justice Sotomayor recognized that "[e]ven if a prisoner can prove that the State plans to kill him in an intolerably cruel manner, and even if he can prove that there is a feasible alternative, all a State has to do to execute him through an unconstitutional method is to pass a statute declining to authorize any alternative method."⁴⁶⁷ It is problematic that a state could legislate its way out of being required to comply with the constitutional rights of individuals. Justice Sotomayor also noted that by "conditioning federal constitutional rights on the operation of state statutes," basic constitutional principles are being violated.⁴⁶⁸

d. Secrecy Statutes

Many states have enacted secrecy statutes.⁴⁶⁹ These statutes conceal the identity of the sources the states use to obtain the drugs for lethal injections.⁴⁷⁰ Secrecy makes it difficult for prisoners to obtain facts necessary to raise an Eighth Amendment method of execution claim under the *Glossip* standard.⁴⁷¹ Since condemned prisoners are required to show that the current method

⁴⁶⁶ Arthur v. Dunn, 137 S. Ct. 725, 729 (2017) (Sotomayor, J., dissenting).

⁴⁶⁷ Id.

⁴⁶⁸ Id.

⁴⁶⁹ Crider, *supra* note 10, at 5.

⁴⁷⁰ *Id*.

⁴⁷¹ *Id.* at 26.

of execution creates a substantial risk of serious harm, they have to know what the current method of execution is, including the source of the drugs.

There are risks associated with obtaining drugs from certain sources, such as compounding pharmacies,⁴⁷² which are not regulated by the federal Food and Drug Administration (FDA).⁴⁷³ In 2018, a compounding pharmacy supplying lethal injection drugs to Missouri admitted to committing over 1800 violations of pharmacy regulations.⁴⁷⁴ These violations include improperly extending drug expiration dates and operating when its lab was not certified.⁴⁷⁵ Without the identity of the sources of drugs, condemned prisoners are not able to discover if the state is obtaining the drugs from a source that carries such risks. Even if prisoners suspect that such risks are present, they are not able to prove the risks exist, due to the nature of the secrecy statutes. In fact, prisoners on Missouri's death row challenged the lethal injection protocol, stating that the drug the state planned to use from a compounding pharmacy may not be sterile, may be less potent than it needs to be, or may be contaminated.⁴⁷⁶ Before the inspection of the compounding pharmacy in 2018, these cases were decided, with the judge stating that the risk the prisoners identified was too speculative.⁴⁷⁷ Now we know that the speculations were true.

⁴⁷⁵ *Id*.

⁴⁷⁶ Id.

⁴⁷⁷ Id.

⁴⁷² *Id.* at 17.

⁴⁷³ Jeffrey Toobin, *Cruel and Unusual*, NEW YORKER (Dec. 30, 2013), https://www.newyorker.com/magazine/2013/12/23/cruel-and-unusual.

⁴⁷⁴ Missouri Execution Drug Supplier Being Sold After Committing Nearly 2,000 Violations of Pharmacy Regulations, DEATH PENALTY INFO. CTR. (Apr. 25, 2016), https://deathpenaltyinfo.org/news/missouri-execution-drug-supplier-being-sold-after-committing-nearly-2-000-violations-of-pharmacy-regulations.

Furthermore, under the secrecy statutes, some states have violated their Freedom of Information Laws and state constitution because of their insistence on withholding information.⁴⁷⁸ Secrecy statutes also reduce predictability and accountability in executions carried out by lethal injection.⁴⁷⁹ For example, in Missouri, the state's Director of the Department of Corrections stated under oath that the state would not use midazolam in its lethal injection protocol.⁴⁸⁰ Despite this testimony, and that of other correctional officers stating the same, Missouri has used midazolam in numerous executions, without disclosing this information to anyone outside of the department of corrections.⁴⁸¹

II. Lethal Injection Drug Protocols

In the majority of states that authorize capital punishment, the lethal injection method used involves a three-drug combination protocol.⁴⁸² The first drug is an anesthetic to render the prisoner unconscious.⁴⁸³ The second drug is a paralytic to stop the prisoner's breathing.⁴⁸⁴ The third drug is used to stop the prisoner's heart, causing death.⁴⁸⁵ The first drug in the three-drug protocol

⁴⁸³ *Id*.

⁴⁸⁵ *Id*.

⁴⁷⁸ McGehee v. Mo. Dep't of Corr., No. 2:18-mc-04138-SRB, 2019 U.S. Dist. LEXIS 10259, at *17 (W.D. Mo. Jan. 15, 2019); *Execution Secrecy Takes a Hit in Court Proceedings in Indiana, Missouri*, DEATH PENALTY INFO. CTR. (Dec. 6, 2018), https://deathpenaltyinfo.org/news/execution-secrecy-takes-a-hit-in-court-proceedings-in-indiana-missouri.

⁴⁷⁹ Crider, *supra* note 10, at 27.

⁴⁸⁰ Chris McDaniel, *Missouri Swore It Wouldn't Use a Controversial Execution Drug. It Did.*, ST. LOUIS PUB. RADIO (Sept. 2, 2014), http://news.stlpublicradio.org/post/missouri-swore-it-wouldn-t-use-controversial-execution-drug-it-did.

⁴⁸¹ *Id.*; Crider, *supra* note 10, at 27.

⁴⁸² State by State Lethal Injection, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/executions/lethal-injection/state-by-state-lethal-injection-protocols (last visited Oct. 23, 2019).

⁴⁸⁴ Lincoln Caplan, *The End of the Open Market for Lethal-Injection Drugs*, NEW YORKER (May 21, 2016), https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs.

ensures the prisoner is executed in a humane manner. Without the anesthetic, the prisoner experiences the excruciating pain caused by the second two drugs, which has been described as the chemical equivalent of burning at the stake.⁴⁸⁶ For the first drug, states originally administered sodium thiopental, which was eventually replaced by pentobarbital.⁴⁸⁷ These drugs are classified as barbiturates and were used to produce unconsciousness to a level comparable to being in a deep coma.⁴⁸⁸ Due to drug shortages, states were forced to change their drug protocols to include other drugs for the first portion of the three-drug protocol.⁴⁸⁹ These include drugs classified as benzodiazepines, such as midazolam.⁴⁹⁰

a. Drug Shortages

Hospira, Inc., the sole manufacturer of sodium thiopental in the United States, ceased production of the drug in 2009.⁴⁹¹ Hospira planned on continuing production in Italy, but the Italian government demanded that the company guarantee the drugs were not going to be used for executions.⁴⁹² Unable to make such a guarantee, Hospira did not manufacture any more sodium thiopental.⁴⁹³ States then obtained the drug from a middleman in London.⁴⁹⁴ This practice was shut

⁴⁹⁰ Id.

⁴⁹³ Id.

⁴⁹⁴ Id.

⁴⁸⁶ Glossip v. Gross, 135 S. Ct. 2726, 2792 (2015) (Sotomayor, J., dissenting).

⁴⁸⁷ Caplan, *supra* note 65.

⁴⁸⁸ Brief of Sixteen Professors of Pharmacology as Amici Curiae in Support of Neither Party at 8, Glossip v. Gross, 135 S. Ct. 2726 (2015) (No. 14-7955), 2015 WL 1247193.

⁴⁸⁹ Eaton, *supra* note 33, at 363.

⁴⁹¹ Crider, *supra* note 10, at 10.

⁴⁹² Toobin, *supra* note 54.

down after the 2012 case of *Beaty v. FDA*, which held that foreign importation of sodium thiopental posed a serious risk of contamination and counterfeit, thereby violating federal Food, Drug, and Cosmetic Act protocols.⁴⁹⁵

Some states changed their drug protocols to include pentobarbital instead of sodium thiopental.⁴⁹⁶ However, Lundbeck, the Denmark based company that holds the patent for pentobarbital, insisted that the drug could not be used for executions.⁴⁹⁷ Missouri enacted a protocol to use propofol as its sole lethal injection drug.⁴⁹⁸ Again, the manufacturer of the drug stated that if the propofol was used in executions, the European Union would impose sanctions that would threaten the entire supply of propofol to the United States.⁴⁹⁹ Therefore, states began getting their drug supplies from compounding pharmacies, which are able to obtain and create drugs without the supervision of the FDA.⁵⁰⁰ Hundreds of civilian deaths and outbreaks of illnesses have been caused by substandard drugs made from compounding pharmacies.⁵⁰¹ Despite these documented risks, courts have held that the use of drugs from compounding pharmacies in lethal injections does not create a substantial risk of harm for condemned prisoners.⁵⁰²

⁴⁹⁹ Id.

⁴⁹⁵ Beaty v. FDA, 853 F. Supp. 2d 30, 42 (D.D.C. 2012), *aff'd in part, vacated in part sub nom*. Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013).

⁴⁹⁶ Toobin, *supra* note 54.

⁴⁹⁷ Lethal Secrecy, REP. COMMITTEE FREEDOM PRESS, https://www.rcfp.org/journals/news-media-and-law-spring-2014/lethal-secrecy/ (last visited Feb. 26, 2019).

⁴⁹⁸ Toobin, *supra* note 54.

⁵⁰⁰ *Id.* ⁵⁰¹ Crider, *supra* note 10, at 17.

⁵⁰² Zink v. Lombardi, 783 F.3d 1089, 1102 (8th Cir. 2015).

In the case of *Gray v. McAuliffe*, the court noted that because previously used drugs in lethal injections were unavailable, the Virginia Department of Corrections approved the use of midazolam as the first drug in the three-drug protocol.⁵⁰³ Midazolam was not approved because of its proven ability to be effectively used in a constitutional manner, but because of the executioner's need to use something for the first drug in the three-drug protocol. The condemned prisoner could not receive a stay of execution based on the speculation of a substantial risk of serious harm. Why, then, can the state execute people based on the speculation that there is not a substantial risk of serious harm?

b. Midazolam

There are many reasons why using midazolam in the three-drug protocol is problematic. Midazolam can be used as a sedative, however, it is not approved by the FDA for use as the sole drug to produce and maintain anesthesia in surgical proceedings.⁵⁰⁴ The American Society of Anesthesiology differentiates sedation from anesthesia.⁵⁰⁵ Sedation is defined as a reduced awareness and response to pain, whereas general anesthesia is a lack of awareness with no response to pain.⁵⁰⁶ Since midazolam is a sedative, the condemned prisoner that receives midazolam will not be rendered unconscious.⁵⁰⁷

⁵⁰³ Gray v. McAuliffe, No. 3: 16CV982-HEH, 2017 U.S. Dist. LEXIS 3606, at *20 (E.D. Va. Jan. 10, 2017).

⁵⁰⁴ Glossip v. Gross, 135 S. Ct. 2726, 2783 (2015) (Sotomayor, J., dissenting).

⁵⁰⁵ Brief of Fifteen Professors of Pharmacology as Amici Curiae in Support of Certiorari at 12, Otte v. Erdos, No. 17-5198, 2017 WL 3142305 (July 24, 2017) (No. 17-5198).

⁵⁰⁶ *Id*.

⁵⁰⁷ Brief of Sixteen Professors of Pharmacology as Amici Curiae in Support of Neither Party at 8, Glossip v. Gross, 135 S. Ct. 2726 (2015) (No. 14-7955), 2015 WL 1247193 [hereinafter Glossip Pharmacology Brief].

Throughout the human body, there are neurotransmitters, which serve a role in the biological functions of the central nervous system (CNS).⁵⁰⁸ Neurotransmitters are chemicals that bind to receptors throughout the body.⁵⁰⁹ This binding causes ion channels to either open or close, resulting in individual neurons becoming excited or inhibited.⁵¹⁰ Gamma-aminobutyric acid (GABA) is an inhibitory neurotransmitter.⁵¹¹ When the brain releases GABA, the GABA binds to GABA_A receptors.⁵¹² This causes chloride ion channels to open, allowing for chloride ions to pass through the channel and into the neuron on which the receptor is based.⁵¹³ The increase in chloride ions in the neuron impedes the flow of electrical impulses in the CNS,⁵¹⁴ thereby inhibiting the neuron and causing depression of the CNS.⁵¹⁵

Midazolam facilitates the binding of the body's naturally occurring GABA to the GABA_A receptors.⁵¹⁶ The resulting influx of chloride ions into the neuron ultimately has a sedative effect.⁵¹⁷ Midazolam can only work as a sedative when there are naturally occurring GABA, and there is a limited amount of naturally occurring GABA in a person's system.⁵¹⁸ Therefore, the drug stops

⁵⁰⁸ Id.

⁵¹⁰ Id.

⁵¹¹ *Id*.

⁵¹³ *Id*.

⁵¹⁶ Glossip, 135 S. Ct. at 2783.

⁵¹⁸ See id. at 18.

⁵⁰⁹ *Id.* at 12.

⁵¹² Glossip Pharmacology Brief, *supra* note 88, at 12.

⁵¹⁴ Glossip v. Gross, 135 S. Ct. 2726, 2783 (2015) (Sotomayor, J., dissenting). *See also* Glossip Pharmacology Brief, *supra* note 88, at 12-13.

⁵¹⁵ Glossip Pharmacology Brief, *supra* note 88, at 13.

⁵¹⁷ Glossip Pharmacology Brief, *supra* note 88, at 15.

having additional sedative effects when there is no more GABA to facilitate chloride ions to inhibit the neurons. Comparatively, barbiturates also facilitate the binding of GABA to the GABA_A receptors, but barbiturates also act as a GABA substitute, mimicking the neuron suppressing effects.⁵¹⁹ Therefore, barbiturates do not need naturally occurring GABA in order to have sedative effects. Because of this, the more barbiturates that a person receives, the more the person will be sedated. Since there is no limit on the effects, barbiturates can act as an anesthetic, rendering a person completely unconscious.⁵²⁰ Comparatively, midazolam is subject to a ceiling effect, meaning that there is a point where increasing the dose will not result in any greater effect.⁵²¹ As a result, midazolam's effect is capped a lower level of sedation, and it cannot render a person unconscious.⁵²² Additionally, unlike barbiturates, midazolam does not have any analgesic effect, meaning it cannot relieve pain.⁵²³

c. Other Drugs

With the shortage of drugs that are normally used for lethal injections, states are substituting the drug protocols with other drugs that have never been used in lethal injections

⁵¹⁹ *Glossip*, 135 S. Ct. at 2783.

⁵²⁰ Glossip Pharmacology Brief, *supra* note 88, at 18.

⁵²¹ Glossip, 135 S. Ct. at 2783.

⁵²² Glossip Pharmacology Brief, *supra* note 88, at 18.

⁵²³ Arthur v. Dunn, 137 S. Ct. 725, 726 n.2 (2017).

previously. These include diazepam,⁵²⁴ fentanyl,⁵²⁵ cisatracurium,⁵²⁶ and etomidate.⁵²⁷ Nevada is currently the only state to authorize the use of diazepam for lethal injections, though it has not used it yet in an execution.⁵²⁸ Nevada is also the only state to authorize the use of cisatracurium and fentanyl in lethal injections.⁵²⁹ Florida is currently the only state to authorize the use of etomidate for lethal injections, as a substitute for midazolam.⁵³⁰

As states continue to search for new drugs for their lethal injection protocol, prisoners' execution sentences may be stayed until drugs become available. This in conjunction with other delays results in years spent waiting on death row. In 2013, the average time between imposition and execution was over fifteen years.⁵³¹

III. Death Row Phenomenon and Death Row Syndrome

Death row phenomenon is a term used to describe "the harmful effects of the conditions experienced on death row, including solitary confinement and the mental anxiety that prisoners experience whilst waiting for their death sentence to be imposed."⁵³² It is the combination of

⁵²⁹ Id.

⁵³⁰ Id.

⁵²⁴ Nev. Dep't of Corr. v. Eighth Judicial Dist. Court, No. 74679, 2018 Nev. Unpub. LEXIS 396, at *4 (Nev. May 10, 2018).

⁵²⁵ Alvogen, Inc. v. State, No. A-18-777312-B, 2018 Nev. Dist. LEXIS 966, at *3 (8th D. Nev. Sept. 28, 2018).

⁵²⁶ Id.

⁵²⁷ Asay v. State, 224 So. 3d 695, 700 (Fla. 2017).

⁵²⁸ State by State Lethal Injection, supra note 63.

⁵³¹ Tracy L. Snell, *Capital Punishment*, 2013 – Statistical Tables, BUREAU OF JUSTICE STATISTICS at 14, https://www.bjs.gov/content/pub/pdf/cp13st.pdf (last updated Dec. 19, 2014).

⁵³² Karen Harrison & Anouska Tamony, *Death Row Phenomenon, Death Row Syndrome and Their Affect on Capital Cases in the US*, INTERNET J. CRIMINOLOGY at 2 (2010), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.371.5070&rep=rep1&type=pdf.

circumstances which prisoners are exposed to when held in solitary confinement on death row.⁵³³ These circumstances include the conditions of imprisonment itself, the length of time spent living under such conditions, and the psychological effects of living with a death sentence.⁵³⁴

Solitary confinement occurs when a prisoner is confined alone within a cell for twenty-two to twenty-four hours a day.⁵³⁵ The psychological effects of solitary confinement are detrimental, leading the USSR, China, and North Korea to use it as a method of torture.⁵³⁶ Various studies have found that solitary confinement often causes conditions including paranoia, hallucinations, self-harm, suicidal thoughts, depression, and loss of a sense of reality.⁵³⁷

The second feature of the death row phenomenon is that the prisoner is awaiting execution. Receiving the death penalty in America comes with a host of other negative consequences besides just death. In 2013, the average time between imposition and execution was over fifteen years.⁵³⁸ Living under a sentence of death for such an extended period of time has debilitating psychological effects.⁵³⁹ Execution dates are often moved due to various factors such as shortages of drugs and pendency of court action. The uncertainty of when the state will execute the prisoner contributes to the death row phenomenon.

⁵³³ *Id.* at 3.

⁵³⁴ Id.

⁵³⁵ Id.

⁵³⁶ *Id.* at 4.

⁵³⁷ Harrison & Tamony, *supra* note 113, at 4.

⁵³⁸ Snell, *supra* note 112, at 14.

⁵³⁹ Harrison & Tamony, *supra* note 113, at 5.

Death row syndrome is "the consequential psychological illness that can occur as a result of death row phenomenon."⁵⁴⁰ While death row syndrome is not yet recognized as an official medical diagnosis, professionals in the medical and psychology field are continuing to research it.⁵⁴¹ Since it is a relatively new concept, there is little legal precedent in the United States on the issue.⁵⁴² However, the anguish condemned prisoners face at the hands of death row has not gone unnoticed by Supreme Court Justices.⁵⁴³ Whether what is now being labeled as death row syndrome is proof of cruel and unusual punishment that is in violation of the Eighth Amendment has not yet been addressed by the Court.⁵⁴⁴

The death row phenomenon has been recognized by international courts. The concept itself can be traced back to *Soering v. United Kingdom*, a 1989 case decided by the European Court of Human Rights.⁵⁴⁵ Soering, a citizen of Germany, was charged with murders in the state of Virginia, and he fled to the United Kingdom.⁵⁴⁶ He argued that the time that he would spend on Virginia's death row would be psychological torture.⁵⁴⁷ The court agreed, and only allowed him to be extradited if the prosecutor did not seek the death penalty, citing the death row phenomenon as their reasoning.⁵⁴⁸

⁵⁴³ *Id.* at 9.

⁵⁴⁶ Id.

⁵⁴⁷ Id.

⁵⁴⁸ Id.

⁵⁴⁰ *Id.* at 2.

⁵⁴¹ Id. at 8.

⁵⁴² Id.

⁵⁴⁴ Harrison & Tamony, *supra* note 113, at 9.

⁵⁴⁵ *Time on Death Row*, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/death-row/death-row-time-on-death-row (last visited Oct. 29, 2019).

a. Lackey v. Texas

The United States has yet to officially or formally recognize death row phenomenon or death row syndrome as cruel and unusual punishment. In 1995, the Supreme Court denied Clarence Allen Lackey's petition for a writ of certiorari, which contended that his execution would be cruel and unusual punishment, since he had been on death row for seventeen years already, awaiting his execution.⁵⁴⁹ Certiorari was denied because the issue was novel, and the Court wanted lower courts to rule on the issue first, making the states "serve as laboratories in which the issue receives further study before it is addressed by" the Supreme Court.⁵⁵⁰ The Court noted that the issue was one of significant importance, because "when a prisoner sentenced by a court to death is confined in the penitentiary awaiting the execution of the sentence, one of the most horrible feelings to which he

b. Aftermath of *Lackey*

Over twenty years after have passed since the *Lackey* decision, and during that time, lower courts have rejected claims that inordinate delay in carrying out an execution constitutes cruel and unusual punishment.⁵⁵² The Supreme Court has also continued to deny certiorari for such claims.⁵⁵³ However, Justice Stevens, Justice Breyer, and Justice Kennedy have continued to write about the

⁵⁴⁹ Lackey v. Texas, 514 U.S. 1045, 1045 (1995) (Stevens, J., respecting denial of certiorari).

⁵⁵⁰ *Id.* at 1047.

⁵⁵¹ Id. at 1045 (quoting In re Medley, 134 U.S. 160, 172 (1890)).

⁵⁵² Angela April Sun, Note, "Killing Time" in the Valley of the Shadow of Death: Why Systematic Preexecution Delays on Death Row are Cruel and Unusual, 113 COLUM. L. REV. 1585, 1595-96 (2013).

⁵⁵³ Id.

cruelty of inordinate delays.⁵⁵⁴ Additionally, many courts outside of the United States that authorize the death penalty have recognized that an inordinate delay is inhumane and cruel.⁵⁵⁵ These include Canada, India, Jamaica, Uganda, and Zimbabwe.⁵⁵⁶

c. Scott Dozier

One recent example of a victim of the death row syndrome is Scott Doizer. On January 5, 2019, Dozier, a death row inmate in Nevada, was found dead in his prison cell after committing suicide.⁵⁵⁷ Dozier had previously appealed his murder conviction and death sentence, but both were affirmed by the Nevada Supreme Court in 2012.⁵⁵⁸ He initially filed a writ of habeas corpus, but he decided to suspend the proceeding and have his death sentence imposed.⁵⁵⁹ Despite this, Dozier's execution was delayed twice because of lawsuits by drug companies in opposition of the drug combination that Nevada planned on using in the executions.⁵⁶⁰ Dozier made statements that life in prison is not life at all, and if the state was going to kill him, he wanted them to go ahead and do it.⁵⁶¹ Because of the years of delay spent waiting in solitary confinement to be executed,

⁵⁵⁹ Id.

⁵⁶¹ Id.

⁵⁵⁴ Thompson v. McNeil, 129 S. Ct. 1299, 1299, 1303 (2009) (Stevens, J., respecting the denial of the petition for writ of certiorari, and Breyer, J., dissenting from denial of certiorari); Knight v. Florida, 528 U.S. 990, 995-96 (1999) (Breyer, J., dissenting from denial of certiorari); Valle v. Florida, 564 U.S. 1067, 1068 (2011) (Breyer, J., dissenting from denial of stay); Sireci v. Florida, 137 S. Ct. 470, 470 (2016) (Breyer, J., dissenting from denial of certiorari); Davis v. Ayala, 135 S. Ct. 2187, 2208 (Kennedy, J., concurring).

⁵⁵⁵ Valle v. Florida, 564 U.S. 1067, 1068 (2011) (Breyer, J., dissenting from denial of stay).

⁵⁵⁶ Death Row Phenomenon, CORNELL L. SCH., http://www.deathpenaltyworldwide.org/death-row-phenomenon.cfm (last updated Jan. 21, 2012).

⁵⁵⁷ Steve Almasy & Madeline Holcombe, *Nevada Death Row Inmate Scott Dozier Dies by Apparent Suicide*, CNN (Jan. 6, 2019), https://www.cnn.com/2019/01/05/us/nevada-death-row-inmate-apparent-suicide/index.html.

⁵⁵⁸ Nev. Dep't of Corr. v. Eighth Judicial Dist. Court, No. 74679, 2018 Nev. Unpub. LEXIS 396, at *2 (Nev. May 10, 2018).

⁵⁶⁰ Almasy & Holcombe, *supra* note 136.

Dozier became suicidal and made several previous attempts to take his own life.⁵⁶² Scott Dozier is just one example of the death row phenomenon that plagues the United States prison system. Suicide rates for death row inmates is higher than that of the average general male prison population and for the general male population outside of prison.⁵⁶³ Having identified these crises that face the American judicial system, there are plausible paths to a solution.

IV. The Role of Congress

Historical attempts at addressing issues within the criminal justice system have failed to address the matters at hand. In 1965, an executive order by President Lyndon Johnson established the Commission on Law Enforcement and Administration of Justice ("Commission"),⁵⁶⁴ mandating a comprehensive review of the criminal justice system.⁵⁶⁵ According to Senator Chuck Grassley, sponsor for the Sentencing Reform and Corrections Act of 2017, there has not been a comprehensive review of the criminal justice system since the 1965 Commission report.⁵⁶⁶ Methods that a country uses to execute its citizens is a human rights issue that receives international attention. In 1995, the Human Rights Committee called on the United States to review its method of execution practices to prevent severe and avoidable pain and suffering.⁵⁶⁷ Additionally, in 2006,

⁵⁶² Nevada Inmate Whose Execution Was Twice Called Off Found Dead in Cell, NBC NEWS (Jan. 7, 2019), https://www.nbcnews.com/news/us-news/nevada-inmate-whose-execution-was-twice-called-found-dead-cell-n955161.

⁵⁶³ Christine Tartaro & David Lester, *Suicide on Death Row*, J. FORENSIC SCI. (Oct. 3, 2016), https://onlinelibrary.wiley.com/doi/abs/10.1111/1556-4029.13069.

⁵⁶⁴ Nicholas Katzenbach, *Foreword* to Challenge of Crime in a Free Society at 2 (1967), https://www.ncjrs.gov/pdffiles1/nij/42.pdf.

⁵⁶⁵ Sentencing Reform and Corrections Act of 2017, S. 1917, 115th Cong. § 302 (2017).

⁵⁶⁶ Id.

⁵⁶⁷ *Methods of Execution*, CORNELL L. SCH., http://www.deathpenaltyworldwide.org/methods-of-execution.cfm (last updated June 22, 2012).

the Torture Committee echoed the call of action set forth by the Human Rights Committee, urging the US to review its methods of executions.⁵⁶⁸

a. President's Commission on Law Enforcement and Administration of Justice

The majority of the Commission's report focused on preventing crime, using rehabilitation as an alternative to incarceration for certain crimes/offenders, providing additional resources to government officials and communities, and continuing research on new methods of controlling crime.⁵⁶⁹ The Commission recommended that the law should have "procedures for review of death sentences that are fair and expeditious."⁵⁷⁰ The report stated that the administration of the death penalty was intolerable because the time between imposition of the death penalty and actual execution averaged four years.⁵⁷¹ In 2013, the average time between imposition and execution was over fifteen years.⁵⁷² With this problem exacerbated, there needs to be reform in the criminal justice system. Although the Commission made a comprehensive review of the criminal justice system, the report did not include any mention of methods of execution.

More recently, in 2013, then Attorney General Eric Holder directed the Department of Justice to make a comprehensive review of the criminal justice system.⁵⁷³ The report prioritized focusing prosecutions of the most important federal cases instead of a large volume of cases,

⁵⁷⁰ *Id.* at 143.

⁵⁷¹ Id.

⁵⁶⁸ Id.

⁵⁶⁹ Challenge of Crime in a Free Society, *supra* note 143, at vi-xi.

⁵⁷² Snell, *supra* note 112, at 14

⁵⁷³ Smart on Crime, DEP'T JUST. at 1 (2013), https://www.justice.gov/sites/default/files/ag/legacy/2013/08/12/smart-on-crime.pdf.

reducing sentences for people that commit low-level, non-violent drug offenses, improving reentry programs, and providing resources to vulnerable populations, such as at-risk youth.⁵⁷⁴ The report did not mention capital punishment in any form.

b. First Step Act

Government involvement has continued to overlook the issues of the methods of executions and the cruel effects of waiting on death row. On December 21, 2018, President Donald Trump signed the First Step Act of 2018, officially making it public law.⁵⁷⁵ The act focuses on reducing recidivism, improving reentry programs, and reducing and restricting enhanced sentences for prior drug felonies.⁵⁷⁶ Additionally, the act restricts juvenile solitary confinement to temporary responses to behavior that pose a serious and immediate risk of physical harm to anyone, including the juvenile.⁵⁷⁷ While this act also does not address methods of execution, the title of the act itself may provide some hope that further acts to reform the criminal justice system are to come. Additionally, it is clear that policymakers are aware of the negative effects that solitary confinement has on juvenile offenders, since it is now prohibited, except in limited circumstances.⁵⁷⁸ Since negative effects are also present in adult inmates subjected to solitary confinement, hopefully the next step will be to change the policies in that area. This could help mitigate the cruel punishment death row inmates experience while awaiting their execution.

⁵⁷⁴ *Id.* at 2-7.

⁵⁷⁵ S.756 - First Step Act of 2018, CONGRESS.GOV, https://www.congress.gov/bill/115th-congress/senate-bill/756/actions?q=%7B%22search%22%3A%5B%22first+step+act+of+2018%22%5D%7D&r=2&s=3 (last visited Jan. 13, 2019).

⁵⁷⁶ First Step Act of 2018, S.756, 115th Cong. § 3631 (2018).

⁵⁷⁷ First Step Act of 2018, S.756, 115th Cong. § 5043 (2018).

⁵⁷⁸ Id.

c. National Criminal Justice Commission

A legislative bill introduced to the Senate in October of 2017 would reform sentencing laws and correctional institutions.⁵⁷⁹ The bill proposed to create a committee that would make "recommendations for changes in Federal oversight, policies, practices, and laws designed to prevent, deter, and reduce crime and violence, reduce recidivism, improve cost-effectiveness, and ensure the interests of justice at every step of the criminal justice system."⁵⁸⁰ Since both the President's Commission on Law Enforcement and Administration of Justice and the Attorney General's Department of Justice commission did not include methods of execution in their review of the criminal justice system, the National Criminal Justice Commission should review capital punishment as a whole, including methods of execution.

The Supreme Court has been hesitant to deem any method of execution as constitutional, due to the issues of separation of power. The Court does not want to act as legislatures. The Court is not always the best equipped to make certain policy and law changes. The legislature has the power to research and fully understand the issues, and they do not have to wait for cases to make new rulings. Congress has the power to invite experts, advocates, and opponents on topics when investigating problems the country faces and how to best remedy those issues.⁵⁸¹ The Senate introduced the First Step Act as well as the Sentencing Reform and Corrections Act.⁵⁸² The

⁵⁷⁹ S.1917 - Sentencing Reform and Corrections Act of 2017, CONGRESS.GOV, https://www.congress.gov/bill/115th-congress/senatebill/1917/text?q=%7B%22search%22%3A%5B%22sentencing+reform+and+corrections+act%22%5 D%7D (last visited Jan. 12, 2019).

⁵⁸⁰ Sentencing Reform and Corrections Act of 2017, S. 1917, 115th Cong. § 303-05 (2017).

⁵⁸¹ *The Legislative Branch*, WHITE HOUSE, https://www.whitehouse.gov/about-the-white-house/the-legislative-branch/ (last visited Feb. 27, 2019).

⁵⁸² First Step Act of 2018, S.756, 115th Cong. (2018); Sentencing Reform and Corrections Act of 2017, S. 1917, 115th Cong. (2017).

legislation produced after the National Criminal Justice Commission reviews the criminal justice system should be the next step to solving the injustices that condemned prisoners currently face through cruel methods of execution as well as cruel inordinate delays in their executions.

Once Congress reviews the report by the National Criminal Justice Commission on the methods of executions currently used by states and whether or not those methods are constitutional, Congress should legislate accordingly. If the current methods of executions that are used are unconstitutional, as this note argues, then Congress should provide legislation to solve the unconstitutionality of the executions. One way that Congress could do this is through its spending power. Additionally, Congress would have the power to create legislation that regulates methods of executions on a national level through the commerce clause. In order for the act of Congress to have the best chance to be upheld, it should cite both its spending power and its power under the commerce clause as justification for the legislation

d. Spending Power

Congress may spend to provide for the common defense and general welfare. General welfare includes any public purpose, and it is not limited to the enumerated powers that Congress already holds. Through its spending power, Congress can require entities that accept government money to act in a certain manner.⁵⁸³ Congress cannot use its spending power for compulsory regulation of subjects within the states' reserved jurisdiction. In other words, Congress cannot invade the rights of the states by attempting to take away power held by the states. Additionally, Congress cannot impose retroactive conditions, only incentives.

⁵⁸³ College Savings Bank v. Fla. Prepaid Postsecondary Ed. Expense Bd., 527 U.S. 666, 686 (1999).
In 2012, the federal government gave out approximately \$278.4 million to states for crime related expenditures, including correctional facilities.⁵⁸⁴ In order for Congress to regulate methods of executions across states under the spending power, it could not take away, or threaten to take away, the current federal funding of state prisons. However, Congress can offer more funding in exchange for compliance with federal regulations. States want more money for prisons, to keep the state safer. Therefore, the incentive for states to comply with federal regulations is high.

e. Commerce Clause

Congress's power under the Commerce Clause falls within three categories: 1) regulation of the channels of interstate commerce; 2) regulation and protection of the instrumentalities of interstate commerce; and 3) regulation of activities that have a substantial effect on interstate commerce.⁵⁸⁵ As for the third category, Congress has the power to regulate any activity, local or interstate, that either in itself or in combination with other activities has a substantial economic effect on interstate commerce.⁵⁸⁶ However, since these activities are not themselves part of interstate commerce, the power to regulate them does not come solely from the Commerce Clause.⁵⁸⁷ Rather, Congress's regulatory authority also derives from the Necessary and Proper Clause.⁵⁸⁸ Additionally, "the regulation of intrastate activities may be necessary to and proper for the regulation of interstate commerce in two general circumstances."⁵⁸⁹ Congress may "facilitate

⁵⁸⁴ Griffin Estes, Note, *RLUIPA and Method-of-Execution Claims After Glossip: The Free Exercise Exception to Glossip's Known-and-Available Alternative Requirement*, 45 HASTINGS CONST. L.Q. 785, 798 n.84 (2018).

⁵⁸⁵ United States v. Lopez, 514 U.S. 549, 558-59 (1995).

⁵⁸⁶ Wickard v. Filburn, 317 U.S. 111, 124-25 (1942).

⁵⁸⁷ Gonzales v. Raich, 545 U.S. 1, 34 (2005) (Scalia, J., concurring).

⁵⁸⁸ *Id.* (citing United States v. Coombs, 37 U.S. 72, 78 (1838)).

⁵⁸⁹ *Id.* at 35.

interstate commerce by eliminating potential obstructions, and . . . restrict it by eliminating potential stimulants."⁵⁹⁰ The refusal of other states to provide information as to how they obtain drugs they use in their legal injection executions has a substantial economic effect on interstate commerce.

As previously discussed, there has been a shortage of drugs that are used in lethal injection protocols.⁵⁹¹ Additionally, in order to succeed on a method of execution claim, a prisoner must prove that there is a readily available alternative method of execution.⁵⁹² Lower courts have held that this standard requires a prisoner to prove that "the State actually has access to the alternative; [and] the State is able to carry out the alternative method of execution relatively easily and reasonably quickly."⁵⁹³

In the case of Thomas D. Arthur, the United States Court of Appeals for the Eleventh Circuit held that Arthur failed to prove that there was a readily available alternative method of execution.⁵⁹⁴ Arthur claimed that the state's plan to execute him using midazolam as the first drug in the three-drug protocol would "create[] a substantial risk of serious harm because . . . there is a high likelihood that midazolam will fail to render [him] insensate from the excruciatingly painful and agonizing effects of the second and third drugs."⁵⁹⁵ Arthur offered, as a readily available alternative, the use of a one-drug protocol of compounded pentobarbital.⁵⁹⁶ Anne Adams Hill,

⁵⁹⁰ Id. (citing NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 36-37 (1937)).

⁵⁹¹ Eaton, *supra* note 33, at 363.

⁵⁹² Glossip v. Gross, 135 S. Ct. 2726, 2739 (2015).

⁵⁹³ Arthur v. Comm'r, Ala. Dep't of Corr., 840 F.3d 1268, 1300 (11th Cir. 2016).

⁵⁹⁴ *Id.* at 1303.

⁵⁹⁵ Id. at 1276.

⁵⁹⁶ Id.

General Counsel for Alabama Department of Corrections (ADOC), testified that Georgia, Missouri, Texas, and Virginia used compounded pentobarbital to execute prisoners.⁵⁹⁷ Further,

Hill testified that she contacted representatives from the departments of corrections in these four states in the fall of 2015 in an effort to obtain compounded pentobarbital. With respect to these four states she recalled asking "specifically if they had compounded pentobarbital and, if they did, if they would be willing to provide it to the [ADOC] and, if not, if they would provide us their source." All four refused.⁵⁹⁸

Hill also contacted seven pharmacies within Alabama, asking "whether they would be willing to compound pentobarbital and provide it to the ADOC, and they all said no."⁵⁹⁹ On May 25, 2017, Arthur was executed.⁶⁰⁰ The state carried out Arthur's execution with midazolam, rocuronium bromide, and potassium chloride.⁶⁰¹

The refusal of other states to provide information as to how they obtain drugs they use in their legal injection executions has a substantial economic effect on interstate commerce. While Congress may not force people to participate in interstate commerce,⁶⁰² it can "facilitate interstate commerce by eliminating potential obstructions."⁶⁰³ The obstruction that states like Alabama face in obtaining drugs for lethal injection protocols can be eliminated by federal regulation of methods

⁵⁹⁹ Id.

⁶⁰¹ Arthur, 840 F.3d at 1274.

⁵⁹⁷ *Id.* at 1279-80.

⁵⁹⁸ Arthur, 840 F.3d at 1280.

⁶⁰⁰ Jenny Jarvie, *Murderer Known as 'Houdini of Death Row' Executed in Alabama*, L.A. TIMES (May 25, 2017), https://www.latimes.com/nation/la-na-alabama-houdini-execution-20170525-htmlstory.html.

⁶⁰² Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2587 (2012).

⁶⁰³ Gonzales v. Raich, 545 U.S. 1, 34 (2005) (Scalia, J. concurring) (citing NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 36-37 (1937)).

of executions. Furthermore, Congress has the power to eliminate these obstructions through the Commerce Clause.

A limitation of federal regulation, based on the principles of federalism, is that Congress may not invade the rights of states. One right that states have is police power. A state's police power allows it to suppress violent crime and vindicate its victims.⁶⁰⁴ For example, Congress has no general right to punish murders committed within any of the states.⁶⁰⁵ Regulating methods of execution is not punishing the crimes of the individuals within states. It is merely the regulation of how the states conduct executions, which is an activity they are already participating in. The regulations ensure the executions are within the constitutional limits. States should still have the policy making power to decide if they have the death penalty, but the method of execution in states that do have the death penalty is of national concern, so the new commission should recommend to Congress and the President that it is treated like one.

Conclusion

The methods that states use to execute condemned prisoners has changed significantly over time, and each method has posed its own challenges in complying with the Eighth Amendment's protection from cruel and unusual punishment. Lethal injection is now the standard method of execution in the US, and it has proven to be problematic. Most states that authorize lethal injection use a three-drug combination protocol.⁶⁰⁶ Due to drug shortages, states have replaced the first drug, which was previously a barbiturate, to benzodiazepines.⁶⁰⁷ There have been multiple botched

⁶⁰⁴ United States v. Morrison, 529 U.S. 598, 618 (2000).

⁶⁰⁵ Id. at 618.

⁶⁰⁶ State by State Lethal Injection, supra note 63.

⁶⁰⁷ Eaton, *supra* note 33, at 363.

executions with this new protocol, specifically with the benzodiazepine midazolam.⁶⁰⁸ As states continue to search for new drugs to execute prisoners, sentences are stayed until drugs become available. This delay results in years spent waiting on death row, which has led to an unproportionate suicide rate in the death row inmate population.⁶⁰⁹

There has not been a comprehensive review of the criminal justice system since the 1965.⁶¹⁰ Even within that report, as well as other related legislation, methods of execution have not been addressed. Methods of execution need to be regulated on a national level, so that there is a fair administration of the death penalty in the states that chose to continue to allow capital punishment. Some prisoners in some states are being executed with drugs that are not available to other states. Those other states are scrambling to find ways to execute their prisoners, and it is resulting in botched, cruel, and unusual punishment. The legislature needs to step up to uphold the Eighth Amendment of the United States Constitution, as it is the legislature's duty to make laws in conformity to constitutional standards.

⁶⁰⁸ Radelet, *supra* note 2.

⁶⁰⁹ Tartaro & Lester, *supra* note 142.

⁶¹⁰ Sentencing Reform and Corrections Act of 2017, S. 1917, 115th Cong. § 302 (2017).

How Far is too Far: Police Use of Consumer Genealogy Databases as a Violation of the Fourth Amendment

Ashley Robinson⁶¹¹

Abstract

In the last decade, genealogy websites like 23andme and GEDmatch have become increasingly popular. These sites have not only become popular with the general public, but police have begun to understand their use and impact in certain unsolved murder and rape cases. The police can take an unknown suspect's DNA, run it through a database like GEDmatch, consult with a genealogist, and determine the identity of a suspect and make an arrest. However, the intrusion that occurs as a result of this search steps into Fourth Amendment territory. This note will address the possible Fourth Amendment violations suffered mainly by the users of these sites, but also possibly the suspects in these cases.

⁶¹¹ Syracuse University College of Law, Juris Doctor expected 2020. I would like to thank Professor Gouldin for her encouragement and help throughout the development of this note.

Introduction

Deoxyribonucleic acid ("DNA") was first discovered and isolated in the 1860s by a Swiss chemist, Johann Friedrich Miescher.⁶¹² With the advancement of technology, our understanding of this molecule has increased tremendously. We now understand that this molecule is the blueprint of life.

DNA is now a staple part of criminal investigations. Police use DNA found at a crime scene to identify suspects and solve crimes. Due to the usefulness of DNA, the FBI created a national database, CODIS (Combined DNA Index System), that holds the DNA profiles of convicted offenders, unknown suspects, and arrestees.⁶¹³ This system is based on the location of 20 core points of a person's DNA called "loci".⁶¹⁴ Geneticists create a CODIS profile for a person by determining their DNA makeup at these loci and uploading that information to the system.⁶¹⁵ As of December 2019, CODIS had produced over 475,803 hits and assisted in more than 465,270 investigations.⁶¹⁶

As our ability to sequence and analyze DNA has advanced, and people's interest in their genetic makeup and family history has increased, new consumer centered genealogy websites

⁶¹⁴ *Id*.

⁶¹⁵ Id.

⁶¹² The Discovery of DNA, YOUR GENOME, https://www.yourgenome.org/stories/the-discovery-of-dna (last visited Sep. 06, 2019).

⁶¹³ Frequently Asked Questions on CODIS and NDIS, FBI, https://www.fbi.gov/services/laboratory/biometric-analysis/codis/codis-and-ndis-fact-sheet (last visited Sep. 6, 2019).

⁶¹⁶ CODIS-NDIS Statistics, FBI (December 2018), https://www.fbi.gov/services/laboratory/biometric-analysis/codis/ndis-statistics (last visited Sep. 06, 2019).

like 23andme and GEDmatch have emerged.⁶¹⁷ These resources are easy, efficient, and informative for a person to understand more about themselves and their family history. They are also helpful to law enforcement.

The police have begun using these sites for some cases when they cannot get a profile match on CODIS. They essentially create a profile for the offender and use the information that they receive, as a starting point to identifying a suspect.⁶¹⁸ They have also enlisted the help of companies like Parabon, who use and interpret the GEDmatch information themselves, and report a possible identity to the police.⁶¹⁹

Initially, the police use of this new technology seems like a positive. But, what about their violation of your privacy? These "searches" by the police, are unconstitutional under the Fourth Amendment. Their search of the database violates the site user's, and possibly the defendant's, Fourth Amendment rights. Although the identification of rapists and murders after twenty years is a positive use of these databases, we must think about this as the first step towards possible police acquisition of our genetic information. This does not mean that the police will be prohibited from using these sites to solve crimes, it just means that they must observe proper Fourth Amendment procedures in order to get the information. It is necessary that we act as soon as possible to preserve the Fourth Amendment rights given to us by the Constitution.

⁶¹⁷ See 23andme, *How it Works*, https://www.23andme.com/howitworks/; see also GEDmatch, GEDmatch Tools for DNA and Genealogy Research, https://www.gedmatch.com/login1.php.

⁶¹⁸ See Tim Arango, Adam Goldman & Thomas Fuller, *To Catch a Killer: A Fake Profile on a DNA Site and a Pristine Sample*, N.Y. TIMES (Apr. 27, 2018), https://www.nytimes.com/2018/04/27/us/golden-state-killer-case-josephdeangelo.html?action=click&module=RelatedCoverage&pgtype=Article®ion=Footer.

⁶¹⁹ See Jacey Fortin, In Serial Rape Case That Stumped Police, Genealogy Database Leads to Arrest, N. Y. TIMES (Aug. 23, 2018), https://www.nytimes.com/2018/08/23/us/ramsey-street-rapist-dna.html.

Common Genealogy Databases and Their Function

Over the past ten years, consumer DNA testing and ancestry research have been on the rise.⁶²⁰ Through these services consumers can sample their saliva at home and receive a DNA report on their ancestry and genetic information.⁶²¹ In addition to the services and sites that process samples of people's saliva, there are additional sites that allow consumers to upload their genetic data in order to help them discover more about their family history.⁶²² 23andme processes your DNA and provides you with a report about your ancestors and specifics on your genetic information, while GEDmatch is a site where you upload a file of your genetic information in order to discover more about your family history.⁶²³

Genetic analysis through 23andme is a simple process that takes about ten weeks in total.⁶²⁴ First, the consumer chooses their service, then 23andme will ship their collection kit.⁶²⁵ Once the consumer receives the collection kit, they spit in the tube provided, register the collection tube, and mail it back.⁶²⁶ About three to five weeks later they can login to their account and "start discovering what [their] DNA says about [them]."⁶²⁷ The various reports

⁶²⁴ 23ANDME, *supra* note 10.

⁶²⁵ Id.

⁶²⁶ Id.

⁶²⁷ Id.

⁶²⁰ How it Works, 23ANDME, https://www.23andme.com/howitworks/ (last visited Jan. 8, 2019).

⁶²¹ *Id*.

⁶²² GEDmatch Tools for DNA and Genealogy Research, GEDMATCH, https://www.gedmatch.com/login1.php (last visited Jan. 8, 2019).

⁶²³ See How it Works, 23ANDME, https://www.23andme.com/howitworks/ (last visited Jan. 8, 2019); see also GEDmatch Tools for DNA and Genealogy Research, GEDMATCH, https://www.gedmatch.com/login1.php (last visited Jan. 8, 2019).

available synthesize information about a person's ancestry, genetic health risks, wellness, carrier status, and other genetic traits.⁶²⁸ The main purpose of this service, is to give the general population access to a simple, quick, and easy service in which they can obtain a personal DNA report with information specific to themselves.⁶²⁹

GEDmatch is a service similar to 23andme, however they do not perform the genetic testing.⁶³⁰ GEDmatch requires a person to upload their DNA and/or their genealogical data (GEDCOM) to use the tools on the website.⁶³¹ GEDmatch is an open-source database which allows anyone to upload and see the results of their personal genealogy information.⁶³² In order to obtain the necessary genealogical data, consumers can use services like 23andme.⁶³³ The data compiled by 23andme is only one avenue for acquiring this information.⁶³⁴ GEDmatch allows amateur and professional researchers, and genealogists to use the information for DNA and genealogical analysis.⁶³⁵ Recently, law enforcement has begun using traditional DNA labs to compile a suspect's genetic information and uploading it to GEDmatch for suspect identification.⁶³⁶

⁶²⁹ Id.

⁶³¹ *Id*.

⁶³³ 23ANDME, supra note 10.

⁶³⁴ Id.

⁶³⁵ GEDMATCH, *supra* note 12.

⁶²⁸ 23ANDME, *supra* note 10.

⁶³⁰ GEDmatch, *GEDmatch.Com Terms of Service and Privacy Policy*, (Revised May 20, 2018), https://www.gedmatch.com/tos.htm (last visited Sept. 5, 2019).

⁶³² Jennifer Huddleston, *Come Back with a Warrant: The Potential Impact of the Carpenter Decision Beyond Cell Phones*, PLAIN TEXT (July 27, 2018), https://readplaintext.com/come-back-with-a-warrant-the-potential-impact-of-the-carpenter-decision-beyond-cell-phones-a307f864b64d.

⁶³⁶ See GEDMATCH TOOLS FOR DNA AND GENEALOGY RESEARCH, <u>https://www.gedmatch.com/login1.php</u> (last visited Jan. 8, 2019); see also Jacey Fortin, In Serial Rape Case That Stumped Police, Genealogy Database Leads to

DNA as an Investigation Aid For Police

DNA is an important tool for police in modern criminal investigations.⁶³⁷ DNA allows the police to include or exclude a suspect from a particular investigation.⁶³⁸ One of the tools police use is the Combined DNA Index System (CODIS).⁶³⁹ This is a national DNA database maintained by the FBI.⁶⁴⁰ Profiles of convicted offenders, arrestees, detainees and unknown suspect samples from crime scenes are stored in this database.⁶⁴¹

In order to use CODIS, a DNA profile of a suspect is created through DNA testing, and the unknown profile of the suspect is searched against the database of arrestee and convicted offender profiles.⁶⁴² Additionally, the unknown profile may be searched against the database of other crime scene profiles.⁶⁴³ If there is a match in either of these circumstances, the laboratory will go through the proper protocol for matching the unknown DNA with a known sample in the

⁶³⁸ Id.

⁶⁴⁰ Id.

⁶⁴¹ Id.

⁶⁴² Supra note 3.

⁶⁴³ Id.

Arrest, THE NEW YORK TIMES (Aug. 23, 2018), https://www.nytimes.com/2018/08/23/us/ramsey-street-rapist-dna.html.

⁶³⁷ Using DNA to Solve Crimes, THE U.S. DEP'T OF JUSTICE ARCHIVES (March 7, 2017), https://www.justice.gov/archives/ag/advancing-justice-through-dna-technology-using-dna-solve-crimes.

⁶³⁹ Combined DNA Index System (CODIS), FBI, https://www.fbi.gov/services/laboratory/biometric-analysis/codis.

database.⁶⁴⁴ Then, only if there is a match, will they be able to obtain the identity of the suspected perpetrator.⁶⁴⁵

The ability of CODIS to create potential matches in DNA profiles rests on the similarity of 20 core loci.⁶⁴⁶ These loci are sections that are identified within the "junk-DNA" regions of a person's DNA that can be used to show patterns of inheritance from one's parent's that is individualized.⁶⁴⁷ "Junk-DNA" is a term scientists use to refer to sections of DNA that does not code for, nor contain information about particular traits or genetic conditions a person may have.⁶⁴⁸ This identification is possible, and significant, because a person inherits a different set of patterns from their mother and their father at each loci.⁶⁴⁹ Scientists can then use statistics and matches between a significant number of the 20 CODIS loci to determine if a person can be included or excluded as a suspect.⁶⁵⁰

CODIS also has extra privacy protections for the DNA profiles that are uploaded.⁶⁵¹ Only certain qualified personnel are allowed access to the database.⁶⁵² Profiles in the database contain no identifying information specific to the person.⁶⁵³ Their profile in the database contains an ID

⁶⁴⁸ Id.

⁶⁴⁹ Id.

⁶⁵⁰ Supra note 3.

⁶⁵¹ Id.

⁶⁵² Id.

⁶⁵³ Id.

⁶⁴⁴ Id.

⁶⁴⁵ Id.

⁶⁴⁶ Supra note 3.

⁶⁴⁷ Ananya Mandal, *What is Junk DNA?*, NEWS MEDICAL LIFE SCIENCES (Aug. 23, 2018), https://www.news-medical.net/life-sciences/What-is-Junk-DNA.aspx.

number that allows the appropriate individuals the necessary information to follow up on confirming the identity of a suspect.⁶⁵⁴ Additionally, there are expungement requirements.⁶⁵⁵ If a participating laboratory receives a certified copy of a court order that states that the conviction was overturned for a convicted offender, or if an arrestee's charge was dismissed, acquitted, or no charges were brought in the required time period, then the profile is expunged from the database.⁶⁵⁶

However, police are moving to new "open-source" databases and collaborate with genealogy experts to solve previously unsolvable cases. ⁶⁵⁷ Police create profiles on GED match with a suspect's DNA profile and work with independent genealogy experts to determine the suspect's identity. ⁶⁵⁸ This is how police identified the Golden State Killer and the Ramsey Street Rapist.⁶⁵⁹

Throughout 1977, residents of Sacramento County tried and failed to identify the Golden State killer who terrorized the community with brutal rapes, assaults, and murders.⁶⁶⁰ Originally, investigators developed a profile of him, "an agile young man, just under 6 feet tall and with a

⁶⁵⁴ Id.

⁶⁵⁶ Id.

⁶⁵⁵ Supra note 3.

⁶⁵⁷ Glen Martin, *Gird Your Genes: What DNA Matching Might Mean for Your Privacy*, CAL. ALUMNI ASS'N U.C. BERKLEY: CALIFORNIA MAGAZINE (July 25, 2018 1:49PM), https://alumni.berkeley.edu/california-magazine/just-in/2018-07-24/gird-your-genes-what-dna-matching-might-mean-your-privacy.

⁶⁵⁸ See Arango et al., supra note 8.

⁶⁵⁹ See Id.; see also Jacey Fortin, In Serial Rape Case That Stumped Police, Genealogy Database Leads to Arrest, N.Y. TIMES (Aug. 23, 2018), https://www.nytimes.com/2018/08/23/us/ramsey-street-rapist-dna.html.

⁶⁶⁰ See Dan Barry, Tim Arango, and Richard A. Oppel Jr., *The Golden State Killer Left a Trail of Horror with Taunts and Guile*, N.Y. TIMES (Apr. 28, 2018), https://www.nytimes.com/2018/04/28/us/golden-state-killer-joseph-deangelo.html?module=inline.

size-9 shoe, whose tactical precision suggested military or law enforcement experience".⁶⁶¹ Advancements in technology led to a discovery in 2001 of a connection between the crimes in Northern and Southern California.⁶⁶² The interest in these cases had their ups and downs over the years, but in 2016 the Sacramento County District Attorney's Office, and the F.B.I., announced a renewed effort to solve these crimes.⁶⁶³

In new efforts, investigators used a never-tested DNA sample of the suspect's DNA and created a fake profile on GEDmatch to try and find a match.⁶⁶⁴ The investigators posed as a new user researching their family history.⁶⁶⁵ The determination of the Golden State Killer's identity was not instantaneous.⁶⁶⁶ The investigators had to enlist the help of skilled genealogists who could understand and interpret the information received.⁶⁶⁷ These scientists took the information from GEDmatch and created a family tree that was filled in using other kinds of data, including birth records and social media profiles.⁶⁶⁸ The investigators and researchers spent about four months using the DNA and genealogy information to identify Joseph James DeAngelo, 72, as the

⁶⁶¹ Id.

⁶⁶² Id.

⁶⁶³ Id.

⁶⁶⁵ Id.

⁶⁶⁶ Id.

⁶⁶⁷ Id.

⁶⁶⁴ See Arango et al., supra note 8.

⁶⁶⁸ Heather Murphy, *How an Unlikely Family History Website Transformed Cold Case Investigations*, N.Y. TIMES (Oct. 15, 2018), https://www.nytimes.com/2018/10/15/science/gedmatch-genealogy-cold-cases.html?rref=collection%2Ftimestopic%2FForensic%20Science&action=click&contentCollection=timestopics&r egion=stream&module=stream unit&version=latest&contentPlacement=2&pgtype=collection.

suspect.⁶⁶⁹ Mr. DeAngelo has now been charged with several murders in Ventura, Orange, and Sacramento Counties.⁶⁷⁰

The Ramsey Street Rapist was identified in a similar fashion to the Golden State Killer.⁶⁷¹ Around a decade ago, Fayetteville, N.C. was terrorized by a series of rapes.⁶⁷² For more than ten years the Ramsey Street Rapist's identity eluded the authorities, until they were able to mine DNA data collected through genealogy websites.⁶⁷³ In this case, the investigating officers were helped by Parabon.⁶⁷⁴ Parabon is a company that now offers forensic genealogy services to law enforcement agencies. They use the independent database, GEDmatch, as a tool.⁶⁷⁵ Parabon uploads the suspect's DNA to GEDmatch and then uses the matches received from the site to construct a family tree that helps the officials find the suspect.⁶⁷⁶ In the Ramsey Street Rapist case, Wayne Bowden, 43, was arrested and now faces dozens of criminal charges in connection with six different rape investigations.⁶⁷⁷

⁶⁶⁹ Id.

⁶⁷⁰ Id.

⁶⁷² Id.

⁶⁷³ Id.

⁶⁷⁴ Id.

⁶⁷⁵ Id.

⁶⁷⁷ Id.

⁶⁷¹ Jacey Fortin, *In Serial Rape Case That Stumped Police, Genealogy Database Leads to Arrest*, N.Y. TIMES (Aug. 23, 2018), https://www.nytimes.com/2018/08/23/us/ramsey-street-rapist-dna.html.

⁶⁷⁶ Fortin, *supra* note 61.

As police use these new genealogy databases to enhance the accuracy and usefulness of their DNA searches, their intrusion into the Fourth Amendment rights of both defendants and users of these sites should be considered.

Defendant's Fourth Amendment Infringement Based on Specific Government Conduct

In order for there to be a Fourth Amendment violation, there has to be a "search".⁶⁷⁸ There are three points in time where there could be a "search" with respect to a defendant. First, when their DNA is taken, either through a buccal swab (cheek swab) or when their DNA is collected from a crime scene. Second, there could be a "search" when the police run a suspect's profile though CODIS. Finally, there could be a "search" when the police create, upload, and analyze a suspect's profile using a service like GEDmatch.

A. The Taking of the Buccal Swab

The Court in *Maryland v. King* decided that where there is a lawful arrest supported by probable cause for one of the specified crimes, the taking and analyzing of a cheek swab of the arrestee's DNA is a "legitimate police booking procedure that is reasonable under the Fourth Amendment."⁶⁷⁹ Prior to King's case, Maryland enacted the Maryland DNA Collection Act which allowed booking personal at police stations to take a buccal swab for a DNA sample from arrestees that were "charged with . . . a crime of violence or an attempt to commit a crime of violence; or . . . burglary or an attempt to commit burglary."⁶⁸⁰ Maryland law specified "a crime of violence to include murder, rape, first-degree assault, kidnapping, arson, sexual assault, and a

⁶⁷⁸ Katz v. United States, 389 U.S. 347, 351 (1967).

⁶⁷⁹ Maryland v. King, 569 U.S. 435, 466 (2013).

⁶⁸⁰ *Id.* at 444.

variety of other serious crimes."⁶⁸¹ King was arrested on assault charges, and his DNA was collected through a buccal swab when he was brought to jail.⁶⁸² His DNA sample was logged into the DNA database and matched the DNA of a rapist from an unsolved rape case.⁶⁸³ King moved to suppress the DNA evidence on the grounds that the taking of the buccal swab was a violation of his Fourth Amendment rights.⁶⁸⁴

However, according to the Court in King:

When officers make an arrest supported by probable cause to hold for a serious offense and they bring the suspect to the station to be detained in custody, taking and analyzing a cheek swab of the arrestee's DNA is, like finger printing and photographing, a legitimate policy booking procedure that is reasonable under the Fourth Amendment.⁶⁸⁵

The slight physical intrusion of the buccal swab is balanced by the state interests of security. ⁶⁸⁶ Therefore, under *King*, the initial taking of a buccal swab from an arrestee who is charged with an appropriate crime, is not a search and does not violate the Fourth Amendment.⁶⁸⁷ However, that is not where the DNA analysis for a defendant ends. Once the swab has been taken, it is then analyzed and run through CODIS.

⁶⁸¹ Id.

⁶⁸² King, 569 U.S. at 440-41.

^{683 569} U.S. at 441.

⁶⁸⁴ Id.

⁶⁸⁵ Id. at 465-66

⁶⁸⁶ See id. at 461.

⁶⁸⁷ King, 569 U.S. at 465-66.

B. The Input of the Defendant's Genetic Profile Into CODIS

The Court in *King* was reluctant to decide on the constitutionality of the CODIS search. However, at the time of the decision, they did specify that the DNA analysis and search of CODIS was only performed on thirteen CODIS loci.⁶⁸⁸ They stated that "...the processing of respondent's DNA sample's 13 CODIS loci did not intrude on respondent's privacy in a way that would make his DNA identification unconstitutional."⁶⁸⁹ However, they stated that "...science can always progress further, and those progressions may have Fourth Amendment consequences."⁶⁹⁰ Although it is possible that the regions of noncoding DNA that are tested may in fact hold genetic information, per CODIS procedures it is not tested for. The Court was concerned that "if in the future police analyze samples to determine…an arrestee's predisposition for a particular disease…not relevant to identity…that case would present additional privacy concerns."⁶⁹¹ The Court in this case was okay with allowing basic testing because of the scientific and statutory safeguards already in place to protect the arrestee's privacy.

In dicta, throughout the opinion, the Court refers to the fact that this is a constitutional search based on the limited amount of expected privacy an arrestee has, and the fact that the database search was limited in scope.⁶⁹² From the comments, or lack thereof, by the Court on the issue of the database search, it is likely that a CODIS search would not be considered a Fourth

⁶⁹⁰ Id.

⁶⁹² *Id.* at 447.

⁶⁸⁸ See id. at 445; see also Frequently Asked Questions on CODIS and NDIS, FBI,

https://www.fbi.gov/services/laboratory/biometric-analysis/codis/codis-and-ndis-fact-sheet (last visited Sept. 6, 2019) (stating that the FBI currently tests for twenty loci).

⁶⁸⁹ King, 569 U.S. at 464.

⁶⁹¹ *Id.* at 464-65.

Amendment "search". The lack of discussion on the topic could lead the Court in the future to determine that the CODIS database searches are too intrusive and may need to be limited. However, the police haven't stopped here. Sometimes the police now continue their search for a suspect with GEDmatch, or a similar service.

C. Suspect's Reasonable Expectation of Privacy of Their Genetic Information

If the police are able to upload an entire genetic profile of an arrestee to GEDmatch, the statutory and privacy regulations of CODIS are not in place. The Court should find this expansion of available data on an arrestee to be a violation of the Fourth Amendment. The Court in *<u>King</u>* reiterated the point that the data that was being used in the case was *only* the identification information from the 13 CODIS loci used to confirm the identity of the person in custody.⁶⁹³ When the police use GEDmatch to find a suspect, their entire family history, and possibly some health information, is uncovered. This information is private and although arrestees have "diminished expectations of privacy", they still have some expectations of privacy.⁶⁹⁴ Where the police create and upload a complete genetic profile of a suspect in order to create a comprehensive familial profile, they are intruding on the suspect's Fourth Amendment rights.

⁶⁹³ King, 569 U.S. at 445.

⁶⁹⁴ *Id.* at 463

The Violation of Genealogy Sites User's Fourth Amendment Rights by the Government

Defendants are not the only people affected by police searches of sites like GEDmatch. The other users of the site have a reasonable expectation of privacy, as identified in *Katz*, over the personal genetic information that they upload to the site.⁶⁹⁵ It is well settled that in order for there to be a Fourth Amendment violation, there has to be a "search".⁶⁹⁶ There are two points in time when a search may occur for the users of these sites. The first is when the saliva sample is taken, and the second is when the police run a search with a suspect's genetic profile through the website. Under the test articulated in *Katz*, for a "search" to be in violation of a person's constitutional rights, the "search" must violate a person's reasonable expectation of privacy.⁶⁹⁷ This reasonable expectation of privacy that "society is prepared to recognize as 'reasonable'".⁶⁹⁹

While *King* specifically addresses the rights of the arrestee's and the police, they also make the point that "DNA identification like that at issue [in the case] does not require consideration of any unique needs that would be required to justify searching the average citizen".⁷⁰⁰ The Court distinguishes between "the search of a citizen who has not been suspected of a wrong, [and] a

⁶⁹⁸ Id.

⁶⁹⁵ Katz v. United States, 389 U.S. 347, 351 (1967).

⁶⁹⁶ Id.

⁶⁹⁷See Id.

⁶⁹⁹ *Id.* at 361.

⁷⁰⁰ King, 569 U.S. at 463.

detainee [who] has a reduced expectation of privacy".⁷⁰¹ The Court is careful to make this distinction. As a citizen that has not been arrested, you have a certain expectation of privacy, a reasonable expectation of privacy.⁷⁰² Arrestees have diminished expectations of privacy.⁷⁰³ Once an individual has been taken into custody the police are allowed to search the person and their immediate property.⁷⁰⁴ These searches are not allowed to be performed on the general law-abiding citizen. Therefore, if the search the police execute in the database can be considered a search, then the users of the site could sue for a violation of their Fourth Amendment rights.

A. Personal Saliva Sample

The first possible point where there could be a "search" is when the users take their saliva sample. This is the first step in entering a genetic profile into these databases. However, this step cannot be considered part of the "search" by the government. This step is performed autonomously by an individual who then sends and reviews their own genetic profile. There is no government involvement with the initial collection of the sample and therefore this step cannot be considered a "search".

When a site user uploads and reviews their own profile there is not an invasion of privacy, however when the police perform this operation under the guise of ancestry research for the purposes of suspect identification, there is a Fourth Amendment violation.

⁷⁰¹ *Id*.

⁷⁰² Katz, 389 U.S. at 361.

⁷⁰³ *King*, 569 U.S. at 463.

⁷⁰⁴ *Id.* at 449.

B. Police Search of GEDmatch and it's Effect on the Users Privacy

Genetic databases such as GEDmatch, are now being used as an additional tool by law enforcement.⁷⁰⁵ Unlike CODIS, whose information input and output is regulated by federal and state law, GEDmatch is an open-source database with no regulations.⁷⁰⁶ When the government uploads a suspect's DNA to GEDmatch, the search they perform involves the personal information of users of the site. These users have a reasonable expectation of privacy over their information. When police use a person's DNA data from these sites, they are infringing on an area of privacy people expect to maintain.

Most people understand that the DNA data they are uploading is a blueprint of who they are. Their DNA codes for everything that happens in their body, and consumers expect this information to be protected and not misused. Justice Harlan in his concurrence in *Katz* stated that "that (a) an enclosed telephone booth is an area where, like a home, and unlike a field, a person has a constitutionally protected reasonable expectation of privacy...."⁷⁰⁷ Here, a person's DNA data is a type of information that can be equated to a person's home. A person's home is a personal and private place where they are able to maintain their own lifestyle how they want.⁷⁰⁸ Similarly, a person's DNA is personal and private information that codes for who they are.

⁷⁰⁵ *Supra* note 12.

⁷⁰⁶ Huddleston, *supra* note 22.

⁷⁰⁷ Katz, 389 U.S. at 361 (Harlan, J., concurring) (internal citations omitted).

⁷⁰⁸ Id.

When people upload this information, they expect it to be used to find family members and explore their genetic qualities and background.⁷⁰⁹ They do not expect this information to be used to narrow down the suspects of a murder case to a family member.⁷¹⁰ Therefore, there is a "search" in this case as it is defined under *Katz*.⁷¹¹

C. The Issue of Consent

If determined that the users of the site consented to this searching by the police, then their Fourth Amendment claim would fail. All of the genealogy databases have a privacy policy. 23andme is a private company that regulates who has access to the information that they hold. After consumers send their saliva to the company, they control how the information is distributed to their clients and others. They state in their privacy policy that "[they] will not provide information to law enforcement or regulatory authorities unless required by law to comply with a valid court order, subpoena, or search warrant for genetic or Personal Information".⁷¹² Through 23andme's privacy policy, it is clear how much information consumers are consenting to share with law enforcement – none unless they have a valid order requiring the relinquishment of the information which would moot the Fourth Amendment violation.

However, GEDmatch is an open-source database whose information distribution is not actually monitored or limited by its owners.⁷¹³ Additionally, GEDmatch's privacy agreement

⁷⁰⁹ Glen Martin, *Gird your Genes: What DNA Matching Might Mean for Your Privacy*, CALIFORNIA MAGAZINE (July 25, 2018, 1:49 PM), https://alumni.berkeley.edu/california-magazine/just-in/2018-07-24/gird-your-genes-what-dna-matching-might-mean-your-privacy.

⁷¹⁰ Id.

⁷¹¹ Katz, 389 U.S. at 360-61 (Harlan, J., concurring).

⁷¹² *Supra* note 10.

⁷¹³ Huddleston Skees, *supra* note 22.

was always vague, stating that its owners had no control over how any individual's genetic or family tree data would be used. After the Golden State Killer was arrested, and the police stated that they used vast amounts of people's genetic information from the site to perform familial matching to locate the killer, GEDmatch updated their privacy policy.⁷¹⁴ Currently their privacy policy states "we may disclose your Raw Data, personal information, and/or Genealogy Data if it is necessary to comply with a legal obligation such as a subpoena or warrant. We will attempt to alert you to this disclosure of your Raw Data, personal information, and/or Genealogy Data, unless notification is prohibited under law".⁷¹⁵ Although, this privacy policy may give users a belief that their information will not be given to law enforcement, that is not true. The police can access the same data the users can under the guise that they too are interested in their family history, when instead they are interested in the identity of a suspect.

Through these privacy statements and the concessions for the transmission of information to law enforcement when required, it may be said that by uploading their genetic information to these sites people are consenting to the distribution of the information to the police, therefore voiding the Fourth Amendment issue. The decision of the Court in *Florida v. Jimeno*, could be read on its surface to support this point.⁷¹⁶ In this case, Jimeno was pulled over for a traffic violation and the police searched his car. ⁷¹⁷ Jimeno wanted the evidence from the search to be suppressed, but the Court found that "it was objectively reasonable for the police to conclude that

⁷¹⁴ *Supra* note 12.

⁷¹⁵ *Id*.

⁷¹⁶ Florida v. Jimeno, 500 U.S. 248 (1991).

⁷¹⁷ Jimeno, 500 U.S. at 249-50. Jimeno was pulled over and the police asked if they could search his car, he consented. The police found a brown paper bag in his car and looked inside the bag and found cocaine inside. Jimeno argued at trial that his consent for the car search did not extend to the search of the bag inside the car.

the general consent to search respondent's car included consent to search containers within that car which might bear drugs. A reasonable person may be expected to know that narcotics are generally carried in some form of a container".⁷¹⁸

However, the Court also stated that the although a consensual search is not a violation of the Fourth Amendment, "the standard for measuring the scope of a suspect's consent under the Fourth Amendment is that of 'objective' reasonableness – what would the typical reasonable person have understood by the exchange [with the officer]".⁷¹⁹ In the case of *Jimeno* it was reasonable for the suspect to expect the officer to go through a bag in his car because the officer was searching for drugs, and that would be a common way to carry drugs.⁷²⁰ However, in the case of the police searches of the genetic databases, the users do not consent to have their information "searched" and used to create familial histories of a suspect in order to determine their identity. Since the standard for measuring "the scope of consent...[is] objective reasonableness" the scope of the search should be what a reasonable person would expect.⁷²¹ Since these sites have privacy policies, and the users of these sites consent to the sites use of their data to help members in the community discover their personal family history, the search by the police officers to identify suspects invades the user's Fourth Amendment rights. The users do not waive their Fourth Amendment rights to the "search" of their information for the police's use in investigations. This "search" is outside the scope of their consent.

⁷¹⁸ *Id.* at 251.

⁷¹⁹ Id.

⁷²⁰ Id.

⁷²¹ *Jimeno*, 500 U.S. at 252.

D. The Effect of the Third-Party Doctrine

The Third-Party Doctrine adds an additional lawyer of analysis. The Third-Party Doctrine has been interpreted to mean that information you voluntarily share with a third-party is not protected by the Fourth Amendment because it cannot be expected that they will keep the information confidential.⁷²² A person has to have a "'justifiable', a 'reasonable,' or a 'legitimate expectation of privacy' that has been invaded by government action" for Fourth Amendment protections to be present where a person has shared information with a third party.⁷²³ When information is shared with GEDmatch and 23andme, the Third Party Doctrine does apply. It is assumed that when you volunteer your information to these websites, you assume the risk that it will be shared with others.

However, last year, the Court restricted the Third Party Doctrine through their decision in *Carpenter v. United States*.⁷²⁴ The Court held that the government's acquisition of Carpenter's cell-site records was a Fourth Amendment "search".⁷²⁵ In this case police officers had arrested multiple men that were suspected to be involved in a series of robberies.⁷²⁶ They requested 152 days of cell-site records, and with this the Government obtained a total of 12,898 location points

⁷²² United States v. Miller, 425 U.S. 435, 440 (1976); Smith v. Md., 442 U.S. 735, 741-45 (1979).

⁷²³ Smith, 442 U.S. at 740.

⁷²⁴ Carpenter v. United States, 138 S. Ct. 2206, 2214 (2018).

⁷²⁵ Id.

⁷²⁶ *Id.* at 2212.

on Carpenter's movements.⁷²⁷ From that information they were able to produce maps of Carpenter's exact locations and pin the crime on him.⁷²⁸

The Court in *Carpenter* made a number of distinctions between that case and the application of the Third Party Doctrine in previous decisions.⁷²⁹ The Court stated that the "'basic purpose of [the Fourth Amendment],'...'is to safeguard the privacy and security of individuals against arbitrary invasions by governmental officials'".⁷³⁰ It also acknowledged that "'a person has no legitimate expectation of privacy in information he voluntarily turns over to third parties'".⁷³¹ However, the Court distinguishes *Carpenter* by the type of information that is in play and the question of "how to apply the Fourth Amendment to a new phenomenon: the ability to chronicle a person's past movements through the record of his cell phone signals".⁷³² The Court decided in this case that the "fact that the information is held by a third party doesn't by itself overcome the user's claim to Fourth Amendment protection".⁷³³

The Court looked to multiple factors in making its decision. One factor was that the amount of information that was available with current technology was too great and complete to be waived under the Third Party Doctrine.⁷³⁴ The Court stated that "much like GPS tracking of a

⁷³² Id.

⁷²⁷ Id.

⁷²⁸ *Id.* at 2213.

⁷²⁹ *Id.* at 2214.

⁷³⁰ Carpenter, 138 S. Ct. at 2213.

⁷³¹ *Id.* at 2216.

⁷³³ *Id.* at 2217.

⁷³⁴ Carpenter, 138 S. Ct. at 2213-14.

vehicle, cell phone location information is detailed, encyclopedic, and effortlessly compiled".⁷³⁵ This fast, easy, and comprehensive acquisition of information is protected as a Fourth Amendment "search".⁷³⁶ The information that people share with companies like GEDmatch, is like the cell phone data in *Carpenter* because it gives law enforcement a "detailed and encyclopedic" amount of information about a person.⁷³⁷ Cell phone data can tell law enforcement a person's exact location at any time during the day.⁷³⁸ Similarly, a person's genetic information can give law enforcement many different pieces of personal information that are arguably more sensitive than a person's location.⁷³⁹ The concern is not only with law enforcement being able to use a person's DNA data to aid in an investigation, but also for who may have access to the data in the future.⁷⁴⁰ If there are no limits on how law enforcement can access and use people's personal genetic information, then it may be more difficult, or too late, to restrict access in the future.

Carpenter's cells site records were also considered to represent an "intimate window into a person's life." ⁷⁴¹ The Court decided "a cell phone [is] almost a feature of human anatomy" and

⁷³⁸ Carpenter, 138 S. Ct. at 2209.

⁷⁴⁰ Id.

⁷³⁵ *Id.* at 2217.

⁷³⁶ See id.

⁷³⁷ See Carpenter, 138 S. Ct. at 2209; See also Mike Godwin, What's Next for the Reasonable Expectation of Privacy?, Slate (June 27, 2018, 3:28 PM), https://slate.com/technology/2018/06/after-the-supreme-courts-carpenter-ruling-where-is-the-reasonable-expectation-of-privacy-heading.html.

⁷³⁹ Mike Godwin, *What's Next for the Reasonable Expectation of Privacy?*, SLATE (June 27, 2018, 3:28 PM), https://slate.com/technology/2018/06/after-the-supreme-courts-carpenter-ruling-where-is-the-reasonable-expectation-of-privacy-heading.html.

⁷⁴¹ Carpenter, 138 S. Ct. at 2209.

that the information from it deserved Fourth Amendment protections.⁷⁴² This surely means that the genetic information of a person, a literal feature of human anatomy, deserves Fourth Amendment protections.

The Court is also obligated to ensure that the progress of science is not allowed to invade and erode the Fourth Amendment protections offered by the Constitution.⁷⁴³ As technology improves and advances, the protections that were originally created need to be interpreted so that they maintain relevance with current technology.⁷⁴⁴ In this case, the capability of labs to mass produce genetic reports for consumers is a valuable service that needs to be protected.⁷⁴⁵ The information that people receive from these services may help them lead longer, healthier, and more productive lives, but they deserve the safety that the constitutional protections from the Fourth Amendment give them.⁷⁴⁶

As our ability to understand more about ourselves advances with science, we should benefit from that information, but we should ensure that our understanding of our constitutional protections is not decreased. The informational sensitivity of the information "searched" should be considered.⁷⁴⁷ The Court has previously held that some records are too sensitive to be warrantlessly collected from third parties, and therefore, the suggestion is advanced that the

⁷⁴² Id.

⁷⁴³ *Id.* at 2223.

⁷⁴⁴ Id.

⁷⁴⁵ Id.

⁷⁴⁶ Id.

⁷⁴⁷ Id. at 2262

Court should adjust the third-party doctrine to account for the necessity of keeping this information private.⁷⁴⁸

The genetic information, in this case, is so detailed and complete that it does satisfy the *Carpenter* exception and is therefore protected under the Fourth Amendment.⁷⁴⁹

E. Was the Government's Search Violative of the Fourth Amendment?

Since in this case there is a "search", the remaining question is "whether the search…conducted in [the] case complied with constitutional standards".⁷⁵⁰ It is necessary for law enforcement to obtain a warrant, a subpoena, or compliance from the person whom they are searching.⁷⁵¹ Harlan noted in his concurrence in *Katz* that "(c) that the invasion of a constitutionally protected area by federal authorities is, as the Court has long held, presumptively unreasonable in the absence of a search warrant".⁷⁵² Even where a search performed by law enforcement or the government would be appropriate, if they do not first get a warrant, subpoena, or compliance from the person then the search is a violation of the person's constitutional rights.⁷⁵³ These safeguards are an important piece of ensuring constitutional protections for people.⁷⁵⁴

⁷⁴⁸ Carpenter, 138 S. Ct. at 2217.

⁷⁴⁹ Carpenter, 138 S. Ct. at 2209.

⁷⁵⁰ Katz, 389 U.S. at 354.

⁷⁵¹ Id.

⁷⁵² Katz, 389 U.S. at 361 (Harlan, J. concurring).

⁷⁵³ Katz, 389 U.S. at 354.

⁷⁵⁴ Katz, 389 U.S. at 356.

In order to have the ability to "search" a database such as GEDmatch or 23andme, law enforcement may need probable cause to comply with the Fourth Amendment requirements.⁷⁵⁵ The problem with the genealogy searches is determining what is enough probable cause, and what is a specific enough search. These databases have large amounts of stored information and sometimes the only way for the government to determine the identity of a suspect is to search the whole database for a match with the hope that relatives of the suspect have uploaded their DNA.⁷⁵⁶ The balance of the needs of the police and the constitutional protections for consumers need to be considered when making this decision.

Conclusion

As we continue to learn more about ourselves through DNA technology, we should embrace the expansion of our understanding. Advanced DNA sequencing technology could be the way we cure cancer or prevent the progression of Alzheimer's. However, we should remain cautious of the ramifications of what DNA information on an individualized and personal level could have in the wrong hands.

Currently, the police are using this information to solve tragic cases and give answers to the families of these victims. However, what will they do with this information in the future? The police have been the first ones to come forward and use this information to advance their criminal investigation objectives but, other groups may follow their suit. If insurance companies or employers were able to have this information, would this enable them to alter their business practices in a negative way?

⁷⁵⁵ Id.

⁷⁵⁶ Supra note 8.

We may have grown accustomed to a decreased level of privacy in our lives, but we must remember that we have constitutional rights under the Fourth Amendment. In order to maintain a level of privacy and security we have to push back on the government. When the police search these databases, they are violating the site user's Fourth Amendment rights, and most likely the suspect's Fourth Amendment rights. We have the right to be "secure in [our] persons, houses, papers, and effects, against unreasonable searches..." and in order to maintain that security these searches by the police must be challenged.⁷⁵⁷

⁷⁵⁷ U.S. CONST. amend. IV.