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Cell-Site Location Data and the Right to Privacy

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I. Does Privacy Right Exist?

The recently decided Supreme Court case *United States v. Jones* underscores the growing debate over privacy rights and government surveillance in the digital age.[1] A cell phone user can be tracked in a few different ways including the global positioning system ("GPS") technology installed on their phone similar to the GPS device used in *Jones* and also through cell site tracking via triangulation. Whether this information, which is stored by the cell phone user's wireless service provider is available to anyone is a question of privacy rights and how the Courts want to interpret them. While this paper focuses mainly on location data recovered as a result of cell site tracking, reference to GPS technology and the governing law are important because the import of the technologies are so similar as they are used for the same purposes and sometimes used together to gather location data.

As of 2005, mobile phones were almost as prevalent as conventional phones with over 195 million cellular subscribers in the United States alone.[2] By advertising

[1] *See* United States v. Jones, 132 S.Ct. 945 (2012).

[2] Matt Richtel, *Live Tracking on Mobile Phones Prompts Court Fights on Privacy*, N.Y. TIMES, Dec. 10, 2005, http://www.nytimes.com/2005/12/10/technology/10phone.html.

applications that turn cell phones into more precise global positioning devices, wireless phone companies exploit cell phones' tracking abilities.[3]

Naturally, technology available to the public is also available to government. Thus, it is of no surprise that law enforcement agencies would want to take advantage of this technology too.[4] As a result, more courts have been asked to determine what legal standard applies when the government wants to use this technology to gather intelligence by tracking an individual.[5] The question becomes, does the government need probable cause or something less?

II. Cell Phone Location Data Has Various Uses.

Cell phone location data (cell cite location data) can be used for many different purposes. In the private sector, one can trace their lost or stolen cell phone from software uploaded on their phone and downloaded on a separate device.[6] From the convenience of their cell phone, the user can access driving directions to a desired location from their current location. A long-haul trucking company can keep track of their fleet of trucks and a taxicab company can determine where their drivers are at any time and in any location.

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[3] Ritchell, *supra* note 2.

[4] *Id*.

[5] *Id.*

[6] Bay City News Service, *Tracking Software leads Oakland police to stolen cell phone, arrests*, Silicon Valley, MercuryNews.com (posted February 17, 2012, updated February 21, 2012)(last visited February 21, 2012) available at http://www.mercurynews.com/breaking-news/ci_19993478.

At the government's end, cell phone location data can be used to determine a precise location from where a 911 emergency phone call was made, responding to the victims faster than ever before.[7] In fact, the Federal Communication Commissions ("FCC") has been a large influence in improving the precision and encouraging the development of cell site location data.[8] The Wireless Communications and Public Privacy Act of 1999 provided the FCC with this foundation and requires wireless telephones to be equipped with locating technology and requires service providers to provided the coordinates - latitude and longitude (within certain ranges) for all emergency calls dialed from a cellular phone.[9] A typical cell phone "will reveal between 20 and 55 location points a day."[10] This data is sufficient to plot the target's movements hour by hour over an extended period of time.[11] "If registration data[12] were also collected by the provider and made available, such records would track the user on a minute by

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[7] Public Safety and Homeland Security Bureau, *Enhanced 9-1-1 Wireless Services,* FCC, available at http://www.fcc.gov/pshs/services/911-services/enhanced911/Welcome.html; Recent Development, *Who Knows Where You've Been? Privacy Concerns Regarding the Use of Cellular Phones as Personal Locators*, 18 HARV. J.L. & TECH. 307, 308 (2004); *see also Understanding Wireless Telephone Coverage Areas*, FCC Consumer Facts, *available at* www.fcc.gov/cgb.

[8] *See* Recent Development, *supra* note 7, at 308-09.

[9] *See* 47 C.F.R. § 20.18(h)(1) (2008); *see* Ken Wallentine, J.D., *Cell Site Location Evidence: A New Frontier in Cyber-Investigation*, 2 AELE MO. L. J. 401, 403 (February 2011).

[10] *Cellular Phone Evidence: Cell Site Location Data*, 13 No. 1 Crim. Prac. Guide 3 (January/February 2012) (citing In re U.S. for Historical Cell Site Data 747 F.Supp.2d. 827, 835 (S.D. TX 2010)[hereinafter *Cellular Phone Evidence*].

[11] *See Cellular Phone Evidence*, *supra* note 10 at 1.

[12] *See* Chamberlain, *infra* note 59 at 1747 and accompanying text; *see* McLaughlin, *infra* note 59 at 426 and accompanying text.

minute basis, compiling a continuous log of [a person's] life, awake and asleep."[13] Government officials have used the data available from tracking cell phones to solve a variety of crimes.

For example, in California, two robbery suspects were located and detained after using a stolen cell phone equipped with Apple's cell phone tracker software.[14] On a larger scale and helping to fight the war on terrorism, the suspect in the 2005 failed suicide bombings was located after he made calls from his cell phone.[15] In another example, the famous Scott Peterson case also presents another example of when cell site location data was used to locate Peterson and bring about justice.[16]

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[13] *See Cellular Phone Evidence*, *supra* note 10 at 1.

[14] Bay City News Service, *Tracking Software leads Oakland police to stolen cell phone, arrests*, Silicon Valley, MercuryNews.com (posted February 17, 2012, updated February 21, 2012)(last visited February 21, 2012) at http://www.mercurynews.com/breaking-news/ci_19993478. The phone was traced by software that one of the victims had installed on his iPad. *Id.* The software was designed to track the phone for this very purpose. *Id.* With this software, the police tracked down two suspects and recovered a vehicle filled with additional stolen goods allegedly used in several additional robberies. *Id.*

[15] *Tracking a suspect by mobile phone*, BBC NEWS (Wednesday, August 3, 2005) at http://news.bbc.co.uk/2/hi/technology/4738219.stm (last accessed January 3, 2012). The Italian police were able to monitor the suspect even though he changed his SIM card while he was on the move. *Id.* The reason is this - a cell phone has two identifiers: (1) the IMSI (International Mobile Subscriber Identity) number, which reveals the user's country code, user account, network code and telephone number, (2) the IMEI (International Mobile Equipment Identity) number which identifies the handset's number "and remains constant even if the SIM card is changed." *Id.* These numbers are reported to nearby base stations. *Id.* Once the information from several of the stations is collected, a geographical location is determined by a triangular calculation between the base stations. *Id.* This calculation can pin point a user's location within a few hundred meters if in an urban area. *Id.*

[16] *See* Diana Walsh & Stacy Finz, *The Peterson Trial: Defendant Lied Often, Recorded Calls Show; Supporters Misled About Whereabouts*, S.F CHRON., Aug. 26 2004, at B1, *available at* http://www.sfgate.com/cgi-bin/article?f=/c/a/2004/08/26/BAG458EJ3S1.DTL.

III. Cell site location data raises concerns about privacy.

Government accessibility to cell phone tracking technology has stirred quite a bit of controversy[17] with concerns about privacy and civil rights at the core of the debate.[18] Specifically, the debate centers over whether use of cell phone tracking technology to gather the whereabouts or "location data" of a suspect necessitates a pre-determination of probable cause to satisfy a warrant application, or if legal use of such technology is satisfied by something less.[19] If the use of cell phone tracking technology to obtain the location data of a suspect is considered a search by definition of the Fourth Amendment and the proceeding years of precedent, then a predetermination of probable cause is necessary, and, only where an exception lies, will the warrantless search pass constitutionality. However, if such use of cell phone location data falls outside the scope of a Fourth Amendment search, the need for probable cause disappears.

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[17] *See Cellular Phone Evidence*, *supra* note 10 at 1 and accompanying text; also *see* Jennifer Grankick, *Can You Track Me Now? Not without a Warrant!*, Law Across the Wire and Into the Cloud Recent Developments in Internet Law *available at* http://blog.zwillgen.com/2011/08/26/can-you-track-me-now-not-without-a-warrant/(last accessed March 3, 2012); *cf.* Bob Brown, *Cornell Prof Warns iPhone, iPad users: "We are selling our privacy," Says cell phone users need to take privacy into account when designing systems*, Network World, April 21, 2011, *available at* 2011 WLNR 8023612; *cf.* David Kravets, Court OKs Warrantless Cell-Site Tracking, Wired.com *available at* http://www.wired.com/threatlevel/2010/09/cell-cite-data/.

[18] J.R. Labbe, *Fortworth Police tracking-tracking system deserves public scrutiny*, Star Telegram at http://www.star-telegram.com/2012/02/27/3767543/fort-worth-police-cellphone-tracking.html (Posted Monday February 27, 2012)(last visited February 28, 2012); *see generally* Am. Civil Liberties Union v. U.S. Dept. of Justice, 655 F.3d 1 (2011).

[19] *See* Richtel, *supra* note 2.

As evidence of the debate in action, some police departments plan on using the technology *after* a determination of probable cause, upon issuance of a warrant.[20] This would be the proper procedure if use of cell cite location data is considered a Fourth Amendment search. If not, policy concerns are worth considering: the probable cause and warrant requirements might present unnecessary hurdles for law enforcement to jump through also, the processes for developing probable cause and applying for a warrant will needlessly use state and federal resources. One former Manhattan prosecutor stated that "[i]t can have a major impact, . . . [i]f I am on an investigation and I need to know where somebody is located who might be committing a crime, or, worse, might have a hostage, real-time knowledge of where this person is could be a matter of life or death."[21]

However, it seems that other departments plan to use the technology to "assist in locating, identifying, and *developing* probable cause and apprehending priority offenders."[22] While to some, this violates privacy at its core; if the use of cell site location data is not a Fourth Amendment search, use of the location data to "develop" probable cause will be perfectly legal subject to state and federal statutes aimed at

[20] *See In re U.S. for Historical Cell Site Data* 747 F. Supp. 2d 827 (S.D. TX 2010); *see also Cellular Phone Evidence*, *supra* note 10, at 1.

[21] *See* Richtel, *supra* note 2.

[22] Labbe, *supra* note 18 (emphasis added). One city recently found itself in a $184, 319.00 debate over whether the city council should approve the Police Department's application for a comprehensive cell-phone tracking system similar to that used by the F.B.I. and U.S. Marshalls Service. *Id.* Privacy and civil rights activists were infuriated after reading memo offered before the city council in support for the tracking system. *Id.* In part the memo stated: "The Police Department will use the KingFish System, a portable tracking-tracking system, to assist in locating, identifying, developing probable cause and apprehending priority offenders." *Id.*

limiting this.[23] According to some government officials, the applicable standard is laid out in the 1994 amendment to the Stored Communication's Act.[24] According to this statute, the government is only required to show "specific and articulable facts" that demonstrate that the records sought are "relevant and material to an ongoing investigation."[25] This standard is much lower than a showing of probable cause.[26] The Pen Register Act has also been used to give magistrates authority to grant applications with something less than probable cause but other limitations do apply.[27] In recent cases, prosecutors have "unsuccessfully argued that the expanded police powers under the USA Patriot Act could be read as allowing cell phone tracking under a standard lower than probable cause."[28] The policy concerns here are best characterized by Justice Douglas when he stated that "[i]f the Warrant Clause were held inapplicable[,] . . . then the federal

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[23] *See* Ian James Samuel, *Warrantless Location Tracking*, 83 NYU L. REV. 1324, 1330-31 (Oct. 2008).

[24] *See* Richtel, *supra* note 2.

[25] 18 U.S.C. §§ 2701-2711 (2000); *see also* Richtel, *supra* note 2.

[26] *Id.*

[27] 18 U.S.C. 3121(a); Interestingly, but outside the scope if this paper, the language of "a separate statute, the Communications Assistance for Law Enforcement Act (CAOEA) says that no order issued 'solely pursuant' to the Pen Register Act may disclose the physical location of the subscriber." *See* Samuel, *supra* note 23, at 1333 (arguing that the act leads one to believe that this standard is only applicable when the statute is used in conjunction with another law which remains unclear); *see* 47 U.S.C. § 1002(a)(2)(2000). The statute states: "[W]ith regard to information acquired solely pursuant to the authority for pen registers and trap and trace devices . . . call-identifying information shall not include any information that may disclose the physical location of the subscriber (except to the extent that the location may be determined from the telephone number);" *see* Samuel, *supra* note 23, at 1333.

[28] Richtel, *supra* note 2.

intelligence machine would literally enjoy unchecked discretion."[29] In support of this argument, one South Texas Magistrate argues that "[p]ermitting surreptitious conversion of a cellphone into a tracking device without probable cause raises serious Fourth Amendment concerns especially when the phone is monitored in the home or other places where privacy is reasonably expected."[30]

IV. Cell phones can reveal data through different technologies.

A. Historical data and real-time data are different in time but related in technology.

When dealing with digital surveillance, the government can choose from two different types of data: historical data and data in real time. Historical data is, in simple terms, data in the past.[31] It is data that will reveal where a person has been at a certain time and place.[32] Often historical data reveals itself in a single form such as where a

[29] United States v. U.S. Dist. Court for E. Dist. of Mich., 407 U.S. 297, 325 (1972)(Justice Douglas' concurring opinion stated that "even the risk of exclusion of tainted evidence would here appear to be of negligible deterrent value, inasmuch as the United States frankly concedes that the primary purpose of these searches is to fortify its intelligence collage, rather than to accumulate evidence to support indictments and convictions. If the Warrant Clause were held inapplicable here, then the federal intelligence machine would literally enjoy unchecked discretion.").

[30] In re Application for Pen Register and Trap/Trace Device with Cell Site Location Authority, 396 F.Supp.2d 747, 765 (S.D. Tex. 2005).

[31] *See* Wallentine, *supra* note 9, at 401, 406, 408.

[32] *Id.* at 404.

single outgoing telephone number was dialed at a single point in time.[33] This data is arguably governed by the Stored Communications Act or even the Pen Register Statute, and is therefore, if a distinction can be made, arguably less deserving of heightened legal scrutiny than real time data (also known as data in motion).[34] Real time data is present time information and is arguably governed by the "super warrants" of The Wiretap Act.[35] This data will typically reveal a user's location as they are moving from one moment to the next. Cell site location data is capable of providing historical "pen register type" data, as well as real-time, moment-to-moment monitoring. While GPS is most known for its real-time surveillance, both technologies offer discrete surveillance.[36] "The distinction between cell site data and information gathered by a tracking device has practically vanished."[37] The goal of the investigation will most likely determine which data law enforcement will choose to apply for. In some cases, law enforcement might find it useful to apply for both.

[33] *See* Wallentine, *supra* note 9, at 404.

[34] *See* Wallentine, *supra* note 9, at 404, 407.

[35] *See* 18 U.S.C. § 2518 (1998). The Wiretap act, on top of a showing of probable cause demands compliance with other procedures as well. This would be the strictest showing.

[36] See Wallentine, *supra* note 9, at 401, 403-06, 408.

[37] *See* Richtel, *supra* note 2.

B. It is important to understand why and how digital surveillance became so available and the differences between the several options.

Cellular service providers, motivated by the Federal Communications Commission ("FCC"), have been providing location information in the context of 911 calls for years.[38] The FCC recognized the need for location information, or the details of an individual's whereabouts, as more and more people began making 911 calls from their cell phones rather than their wired telephones.[39] Among the advancing technologies, service providers typically use one of the following three technologies to "pinpoint" the locations of their subscribers: nearest sensor technology, global positioning system ("GPS") technology, or signal triangulation.[40]

1. Nearest Sensor Technology fails to provide law enforcement with desired precision.

[38] *See* Recent Development, *supra* note 7, at 308.

[39] Recent Development, *supra* note 7, at 308 (stating that "the difficulties presented by cell phone emergency calls led the Federal Communications Commission ("FCC") to set a deadline after which cell service providers must supply location information so that emergency callers can be located within 150 meters").

See also Federal Communications Commission, *Wireless 911 Services, Guide* at http://www.fcc.gov/guides/wireless-911-services (last visited Feb. 3, 2012) (detailing how services providers must comply by providing a "list of counties and portions of counties, that they seek to exclude from the location accuracy requirements . . . because of either heavy forestation or the inability to triangulate a caller's location); *see also* 911 Service, 47 C.F.R. § 20.18 (2004) (mandating licensees to "achieve 95 percent penetration of location-capable handsets among [their] subscribers" by December 31, 2005).

[40] *See* Recent Development, *supra* note 7, at 308.

The simplest and most commonly used technology by wireless service providers is nearest sensor technology.[41] Nearest sensor technology provides location information by determining the single access point or cellular base station to which a cell phone is associated.[42] This technology bases its location information on an assumption that the sensor that the cell phone is associated with is the closest sensor to the cell phone.[43] Working within a three dimensional diameter of the 360-degree radiation 'cell' surrounding the sensor, the base station then computes how far the signal radiates.[44] This technology is the least precise of all the location tracking technologies but is nevertheless utilized.[45]

2. Global Positioning Technology provides the most precision but is not as accessible to law enforcement as other available resources.

Global positioning technology is "an aerospace technology that uses satellites and ground equipment to determine position anywhere on earth."[46] GPS technology enables providers to

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[41] Joanie Wexler, *All About Wi-Fi Location Tracking: Finding things is easy with Wi-Fi,* TECHWORLD (April 4, 2006), http://features.techworld.com/mobile-wireless/2374/all-about-wi-fi-location-tracking/ (last visited Feb. 3, 2012).

[42] *Id.*

[43] Wexler, *supra* note 41.

[44] *Id*.

[45] *Id.*

[46] Smithsonian National Air and Space Museum, *GPS: A New Constellation*, *available at* http://www.nasm.edu/gps/ (last visited Feb. 3, 2012) [hereinafter Smithsonian]. Recent Development, *supra* note 7, at 308-10.

precisely identify the location of a GPS enabled cell phone anywhere in the world.[47] In a simple explanation, "GPS works by measuring the time it takes for a signal to travel the distance between satellites and a cell phone's GPS chip. When the GPS chip receives four synchronized signals from GPS satellites, it can calculate a three-dimensional location that is accurate within 20 meters." [48] In some cases, GPS technology "combine[s] triangulation with a measurement called time difference of arrival (TDOA) over a network of satellites"[49] TDOA measures the relative time delay of signals arriving and received by different cell towers and is compatible in a network of triangulation.[50] "Because time is proportional to the distance traveled, the distance to each sensor within range can be estimated and, consequently, the location of the [cell phone user]."[51] Apple's iPhone and the Android network both use GPS technology for tracking the stolen or lost phones, and GPS technology, while making its way into the smart phone arena, is the least employed technology of the three mentioned in this article because it is the most expensive and not yet available on all cellular phones.

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[47] *See* Recent Development, *supra* note 7.

[48] Smithsonian National Air and Space Museum, How Does GPS Work?, at http://www.nasm.si.edu/exhibitions /gps/work.html (last visited Feb. 3, 2012); *see* Recent Development, *supra* note 7; *see* Smithsonian National Air and Space Museum, GPS In More Detail, at http://www.nasm.edu/gps/spheres.html (explaining the "four synchronized signals as spheres: "Three spheres are necessary to find position in two dimensions, four are needed in three dimensions."); Recent Development, *supra* note 7, at 308-10.

[49] *See* Wexler, *supra* note 41.

[50] Wexler*, supra* note 41.

[51] *Id.*

[52]

3. Triangulation is the most common cell phone tracking technology used by law enforcement authorities.

The focus of the article is on the privacy rights akin to information received from cell site location information collected by third party service providers. This technology most commonly comes in the form of signal triangulation. Like nearest sensor technology and GPS technology, signal triangulation technology is also capable of locating the position of the cell phone user, but instead of obtaining the user's location by assessing the radius surrounding a single cellular base station or receiving a direct satellite communication, detailed positioning information is obtained from a cell service provider's service towers.[53] Cell towers are also known as cellular base stations or cell sites.[54] The information gathered from these cell sites is referred to as cell site location information.[55] "Triangulation," for purposes of cell site location information,

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[52] *A GPS (Assisted GPS)*, NAVI-GADGET.COM, http://www.navigadget.com/wp-content/postimages/2007/01/a-gps-944.jpg (last visited Nov 2011). A GPS is different from regular GPS because it is supported by an assistance server that helps share the tasks of a single GPS network. *Id.* This speeds up the process. *Id.* Mobile networks are often the go to for Assistant Servers. *Id.*

[53] *See* Recent Development, *supra* note 7.

[54] *Id.*

[55] *Id.*

measures the angels between three or more nearby cell sites.[56] The point at where the angles intersect is calculated as the client location or the position closest to the device, and is usually within 50 meters of the actual cell phone location.[57]

[58]

The process where cellular phones communicate with nearby service towers is called registration.[59] As long as the cell phone is powered on, the process of communication remains continuous and automatic.[60] In other words, the cellular user does not have to do anything for the communications between the towers to repeatedly occur.[61] Thus, despite cell phone users not

[56] *See* Wexler, *supra* note 41.

[57] *Id.*

[58] Nabanita, *iPhone records your position on the sly*, GadgetsLane.com(April 25, 2011) at http://www.gadgetslane.com/wp-content/uploads/2011/04/iPhone-with-GPS.jpg (last accessed February17, 2012).

[59] Patrick T. Chamberlain, *Court Ordered Disclosure of Historical Cell Site Location Information: The Argument for a Probable Cause Standard*, 66 WASH.& LEE L. REV. 1745, 1747 (Fall 2009); *see* Kevin McLaughlin, Note, *The Fourth Amendment and Cell Phone Location Tracking: Where are We?,* 29 HASTINGS COMM. & ENT. L.J. 421, 426 (2007) (detailing the process of "registration," in which cellular phones "relay their locations to cellular towers").

[60] Chamberlain, *supra* note 59, at 1747; McLaughlin, *supra* note 59, at 426 (noting that registration "occurs roughly every seven seconds when the cell phone is turned on.").

[61] Recent Development, *supra* note 7, at 309 ("Even when users are not making or receiving calls, cell phones communicate with the nearest cell tower to register.").

dialing out or answering incoming calls, cell phones continue to communicate with the nearest cell tower to "register."[62] For identification purposes, each cell phone has two different types of numbers: a Mobile Identification Number ("MIN") and an Electronic Serial Number ("ESN").[63] A MIN is the ten-digit number another caller dials to call a cell phone--in plain terms this is the caller's telephone number.[64] By contrast, an ESN is a unique, unchangeable number assigned by the manufacturer.[65] To maintain outgoing calls and ensure delivery of incoming calls, the cell phone device must periodically notify the network service provider of the call locations.[66] As soon as the cell phone "registers" its MIN and ESN with a particular cell, the service provider then sends incoming calls directly to the cell.[67] As a cell phone user continues to travel to new locations, the cell phone continues to re-register.[68] However, once the cell phone is powered off, "the registration with a particular cell expires."[69] From this continuous communication, cellular service providers collect detailed information regarding the tower locations relied upon by the cellular users, "which in turn can provide a relatively detailed picture of those users' geographic whereabouts."[70]

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[62] Recent Development, *supra* note 7, at 309.

[63] *Id.*

[64] *Id*.

[65] *Id.*

[66] *Id*.

[67] Recent Development, *supra* note 7, at 309.

[68] *Id*.

[69] *Id*.

[70] Chamberlain, *supra* note 59, at 1747; *see also Cellular Phone Evidence*, *supra* note 10, at 1.

As technology revealing location information has advanced, law enforcement has found great value in its use beyond responding to 911 calls. As previously discussed, law enforcement has used GPS technologies to track drug traffickers, terrorists and killers, law enforcement has also turned to cell site location data technologies to help with catching criminals and in some cases saving lives.[71] In simple terms, the policy question resides in the tradeoffs between the protections of digital surveillance and Fourth Amendment Privacy Rights. How much privacy is society willing to give up?

IV. Overview of Surveillance techniques and applicable law

If the government wants to learn about a person, it is equipped with an array of resources to choose from. Aside from the traditional "steak-out," advances in technology have led to surveillance options like wiretaps for telephonic and computer communication, beepers, pen registers, GPS, and cell site location tracking. However, it must use these resources within the parameters of the law.[72]

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[71] *See generally* United States v. Jones, 132 S.Ct. 945 (2012) (involving the government's use of GPS technologies to establish probable cause to arrest a suspected drug trafficker); (discussing how the government's use of GPS technology helped catch Scott Peterson in the Lacy Peterson Murder); *see also* Recent Development, *supra* note 7, at 310-11; *see also* Chamberlain, *supra* note 59, at 1747 ((stating that CSLI has great utility for law enforcement)(citing Recent Development, *supra* note 7, at 310-11)).

[72] Electronic Frontier Foundation, *Surveillance Self-defense: What Can the Government Do?* https://ssd.eff.org/your-computer/govt (last accessed January 3, 2012).

A. What are Fourth Amendment Privacy Rights?

The Fourth Amendment is the most important law that governs the employment of these resources and states that:

> "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."[73]

A seizure is said to occur when the government takes complete control over an item or person.[74] And, until recently, a search was defined as "any intrusion into something in which one has a reasonable expectation of privacy."[75] The Fourth Amendment's requirement of reasonableness mandates that all searches and seizures that violate this requirement can only proceed upon application and receipt of a validly executed search warrant.[76] A warrant is considered valid upon a determination of probable cause, which is then presented to and approved by a "neutral and detached decision maker."[77] But for an exception to the general warrant requirement[78], the evidence recovered as a result of an unlawful search or seizure will

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[73] U.S. Const. amend. IV.

[74] Electronic Frontier Foundation, *supra* note 72.

[75] *Id.*

[76] *Id.*

[77] *Surveillance Self-defense: Search Warrants,* ELEC. FRONTIER FOUND., https://ssd.eff.org/your-computer/govt/warrants (last accessed January 3, 2012).

[78] *Surveillance Self-defense: Warrantless Searches,* ELEC. FRONTIER FOUND., https://ssd.eff.org/your-computer/govt/warrantless (last accessed January 3, 2012) (wherein exceptions include: the plain view doctrine, exigent circumstances, and the harmless error rule).

not survive the vigors of suppression.[79] Though in many situations the exclusionary rule[80] proves effective in deterring unlawful government conduct, the deterrent effect might not be as potent in situations involving certain surveillance techniques like wiretapping or cell site location data.[81] Relevant to this discussion is the historical development of the Fourth Amendment's application particularly as it applies to surveillance.

B. To understand current Fourth Amendment jurisprudence, it is important to understand past Fourth Amendment jurisprudence.

The United States Supreme Court recently reminded the government that the Fourth Amendment was originally founded in concepts of property law.[82] Resolving whether the installation of a GPS device on a target's vehicle for the purpose of monitoring the vehicle's movements constitutes a search in violation of the Fourth Amendment, Justice Scalia expressed "no doubt that such a *physical intrusion* would have been considered a 'search' within the

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[79] Electronic Frontier Foundation, *supra* note 72.

[80] The exclusionary rule mandates that evidence obtained in violation of the Fourth Amendment shall be excluded but for an exception to the rule. *See* Weeks v. United States, 232 U.S. 883 (1914) (holding that a man's house is his castle protected from unlawful searches and seizures, seized lottery tickets collected as a result could not be used as evidence). This was one of the first applications of the exclusionary rule. *Weeks v. United States*, OYEZ *available at* http://www.oyez.org/cases/1901-1939/1913/1913_461 (last visited February 4, 2012).

[81] United States v. United States District Court, 407 U.S. 297, 325 (1972) (Justice Douglas' concurring opinion stated that "even the risk of exclusion of tainted evidence would here appear to be of negligible deterrent value, inasmuch as the United States frankly concedes that the primary purpose of these searches is to fortify its intelligence collage, rather than to accumulate evidence to support indictments and convictions. If the Warrant Clause were held inapplicable here, then the federal intelligence machine would literally enjoy unchecked discretion.").

[82] *See* United States v. Jones, 132 S.Ct. 945, 947, 949, 951 (2012).

meaning of the Fourth Amendment when it was adopted."[83] Rooted in concepts of traditionalism and framers' intent, Scalia quotes the foreshadowing of Lord Camden from the famous 1765 case *Entick v. Carrington*.[84]

> "Lord Camden expressed in plain terms the significance of property rights in search-and-seizure analysis: '[O]ur law holds the property of every man so sacred, that no man can set his foot upon his neighbor's close without his leave; if he does he is a trespasser, though he does no damage at all; if he will tread upon his neighbour's ground, he must justify it by law.'"[85]

A first reading of this opinion might persuade one to think that the Court is reverting back to a pre-1960's Fourth Amendment reading; however, at second glance, Scalia is clear to qualify his reasoning based upon the specific facts[86], and states that the "reasonable expectation of privacy" that may be at issue in this case is unreviewable for lack of preservation.[87] The Majority may have declined to reach as far as other Courts have in the past, however the concurring justices, fearful that this opinion might be misinterpreted, held firmly to the infamous "reasonable expectation of privacy" analysis, first identified by Justice Harlan in his concurring opinion in *Katz v. United States*.

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[83] *Jones*, 132 S.Ct. at 949 (emphasis added).

[84] *Id.* (quoting Brower v. County of Inyo, 489 U.S. 593, 596 (1989) (quoting *Boyd v. United States*, 116 U.S. 616, 626 (1886); Entick v. Carrington, 95 Eng. Rep. 807 (C.P. 1765).

[85] United States v. Jones, 132 S.Ct. 945, 949 (2012) (quoting *Brower*, 489 U.S. at 596) (quoting *Boyd*, 116 U.S. at 626; *Entick*, 95 Eng. Rep. at 817).

[86] *Jones,* 132 S.Ct. at 945. The specific issue referred to in this case only begs the question whether a comparable trespassory Fourth Amendment search occurred when the government installed a GPS on a suspect's car. *Id.* Though the Court did not discuss whether the defendants had a reasonable expectation of privacy, the lower court hinted at this as a problem. *Id.*

[87] *Jones*, 132 S.Ct. at 945.

C. *Katz v. United States* explains that a "reasonable expectation of privacy" must exist for there to be a search.

In *Katz*, a wiretap was placed on a payphone that was located in a telephone booth. While it is true that there is no right to privacy in those areas that are public, the Court held that as a man has a right to privacy behind the doors of his own home,[88] he also has a right to privacy in those areas that he expects to be private.[89] Jumping over the hurdle that the phone booth is public, the Court analogized his relation to the phone booth as one of a baillee or renter.[90] For the time that he paid his money and shut the door, he owns that space.[91] Though the walls of the booth might be glass, when closed up, the booth becomes private from the rest of the world.[92] Where one walks inside a telephone booth and purposely shuts the door, he is said to believe that his communications will not be overheard by anyone just passing by.[93] This was declared an invasion into his personal space.[94] Expanding upon the holding, Justice Harlan concluded, that communications inside a closed phone booth are an interest that society is ready to protect.[95]

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[88] Weeks v. United States, 232 U.S. 883 (1914).

[89] Katz v. United States, 389 U.S. 347 (1967).

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] *Katz*, 389 U.S. at 347.

[95] *Id.*

Thus declared finding his argument rooted in a "reasonable expectation of privacy" test that Courts later struggled to define.[96]

In *United States v. Karo*, the Supreme Court was asked to decide whether the physical application of a beeper placed on a can of ether, later sold to the suspect and used to track the movements of the cocaine dealers over a period of several months amounted to a search under the Fourth Amendment.[97] This form of tracking did not amount to a search, since the can was traceable on the open roads and then later kept in a storage locker at commercial storage house.[98] The Court held that the ability of law enforcement to pinpoint a specific storage house in a warehouse lacked the precision to defeat the suspect's expectation of privacy in their own storage locker.[99] Yet, when the can of ether was traced back to a private residence, not open to the public, such warrantless tracking violated the Fourth Amendment.[100]

Smith v. Maryland is another important case that fleshes out "the reasonable expectation of privacy" test.[101] In that case, the Supreme Court held that the use of a pen register was not a search because the defendant lacked any reasonable expectation of privacy in the phone numbers he willingly dialed.[102]

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[96] *Katz*, 389 U.S. at 347.

[97] United States v. Karo, 468 U.S. 705, 707 (1984); *see also Cellular Phone Evidence*, *supra* note 10, at 1.

[98] *Karo*, 468 U.S. at 705.

[99] *Id.* at 708.

[100] *Id.* at 714.

[101] *See* Smith v. Maryland, 442 U.S. 735, 738-40 (1979).

[102] *See id.* at 745-46. Responding to privacy concerns, Congress quickly enacted the Pen Register Statute to protect against police abuses of such location data information.

V. The intermediate courts struggle to find common ground.

The Supreme Court has remained silent as to whether the warrantless use of cell site location data is constitutional, but the Appellate Courts are making some noise. In 2010 a Texas court of appeals decided "whether investigators could compel cellular service carriers to provide cell site information for targeted phones over a sixty-day period without obtaining a warrant."[103] The court acknowledged that "although GPS (satellite) tracking can locate an individual within 10 meters[104] of his location, network (cellular) tracking is more pervasive and practical in criminal investigations, due to the limitations of GPS. Those limitations include the fact that older cell phone models lack the equipment for GPS; GPS works reliably only outdoors, where the handset cell phone has an unobstructed view of several GPS satellites in the sky above and that GPS can be disabled by the cell phone user."[105]

Furthermore, "because the size of a typical cell has been decreasing as more towers are built, and because of Congressional mandates to develop wireless location technology in order to enhance the nation's emergency response system, network tracking is becoming increasingly more precise."[106] Following the guidance of Karo[107], the court found that sixty days of

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[103] *See* In re U.S. for Historical Cell Site Data*,* 747 F.Supp.2d 827, 846 (S.D. T.X. 2010); *see Cellular Phone Evidence*, *supra* note 10, at 1.

[104] Some sources report that GPS can pinpoint a user's location within twenty meters. Smithsonian National Air and Space Museum, *supra* note 48.

[105] *See* In re U.S. for Historical Cell Site Data, 747 F.Supp.2d 827, 832 (S.D. Tex. 2010); *see also Cellular Phone Evidence*, *supra* note 10, at 1.

[106] *See* In re U.S. for Historical Cell Site Data, 747 F.Supp.2d 827, 833 (S.D. Tex. 2010); *see Cellular Phone Evidence*, *supra* note 10, at 1.

[107] *See supra* notes 97-100 and accompanying text.

warrantless cell phone tracking using modern technology was much more intrusive than the *Karo* beepers.[108] For this reason the district court concluded that "court decisions allowing the government to compel cell site data without a probable cause warrant were based on yesteryear's assumption that cell site data (especially from a single tower) could locate users only imprecisely."[109] Notably, the court denied an application for appeal.[110]

Conversely, in New York, a federal district judge denied a probable cause mandate and accepted the government's hybrid theory combining the standards of both the Stored Communications Act[111] and the Pen Register and Trap and Trace Device,[112] which together, deliver a standard of "relevance and materiality" to a government request for telephone number tracking.[113] In 2010, another court accepted the "relevant and material" argument stating that the

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[108] *See* In re U.S. for Historical Cell Site Data, 747 F.Supp.2d 827, 837 (S.D. Tex. 2010); *see also Cellular Phone Evidence*, *supra* note 10, at 1. The *Karo* court declined to find a search when the beeper located a storage locker but could not pin point the precise location within. *See* Karo, 468 U.S. at 705.

[109] In re U.S. for Historical Cell Site Data, 747 F.Supp.2d 827, 837 (S.D. Tex. 2010); *see Cellular Phone Evidence*, *supra* note 10 at 1.

[110] *See* In re U.S. for Historical Cell Site Data, 747 F.Supp.2d 827, 837 (S.D. Tex. 2010); *see also Cellular Phone Evidence*, *supra* note 10 at 1.

[111] 18 U.S.C. §2703(c)(1)(2009); *see* Wallentine, *supra* note 9, at 404-05 (2011).

[112] Electronic Communications Privacy Act, 18 U.S.C. §§ 3121-3127 (2006); *see* Wallentine, *supra* note 9, at 404.

[113] *See* In re Application of the U.S. for an Order for Disclosure of Telecommunications Records & Authorizing the Use of a Pen Register & Trap & Trace, 405 F.Supp.2d 435, 449 (S.D.N.Y. 2005); *see* Wallentine, *supra* note 9, at 404.

Stored Communications Act was vague in reference to what standard would apply, but that the statute itself could be interpreted as not requiring a warrant.[114]

VI. United States v. Jones provides little guidance as it stands.

As recent as 2012, the Supreme Court dodged an analogous "reasonable expectation of privacy" argument when it decided the *United States v. Jones* case. The case discusses the legality of physically installing a GPS device on a suspect's car for the purposes of tracking that suspect's movements without a warrant.[115] While the majority of the justices found the physical installation of a GPS device to be a search deserving of probable cause, they were split in their reasoning.[116] The majority opinion reasoned that because the Government failed to preserve the argument regarding whether a reasonable expectation of privacy exists in the continuous monitoring of cell-site location tracking, the physical, tangible intrusion of the device installation for the purposes of monitoring was the only issue to be discussed. Thus, this case did not fall under the *Katz* line of reasoning and the decision therefore was founded in Fourth Amendment property rights.[117] As a result, *Jones's* majority opinion provides little guidance.

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[114] David Kravets, *Court Oks Warrantless Cell-Site Tracking*, The Wire.com, (Sept. 7, 2010), http://www.wired.com/threatlevel/2010/09/cell-site-data/.

[115] United States v. Jones, 132 S.Ct. 945 (2012).

[116] *Id.*

[117] *Id.*

VII. Conclusion: The Need for Uniformity

The ACLU has brought urgency to the need for uniformity. In September 2011, the ACLU filed an appeal asking the Courts to force the government to turn over information relating to all investigations where cell-site location data was used without a warrant.[118] While this decision has no legal implications on the debate, it demonstrates that civil activists are on the move to ensure that privacy rights remain protected, even if the information is stored and openly available to third parties.

In response to the courts' split decisions, a privacy lawyer for the Electronic Frontier Foundation summed up the only workable solution: "What we need at this point is a clear, nationwide standard when it comes to government access to this personal information."[119] The courts, with their hodge-podge of decisions have made it clear that the current statutes that could encompass cell-site location tracking and precedent that somewhat relates to cell-site location tracking are ambiguous at best. Without a new statute that considers the expanding nature of digital surveillance under the cloud of Fourth Amendment privacy, the courts will continue to be divided.

[118] *See generally* Am. Civil Liberties Union v. U.S. Dept. of Justice, 655 F.3d 1 (2011).

[119] Kravets, *supra* note 114.

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The Fight for Accessible Formats: Technology as A Catalyst for a World Effort to Improve Accessibility Domestically

Mary Bertlesman

Abstract

This note addresses the proposed WIPO International Instrument on the Limitations and Exception for Persons with Print Disabilities. I conclude that the current growth in technology - making previously inaccessible works accessible – calls for a change to current domestic copyright law and that ratification of the proposed treaty should be this change.

The proposed treaty compliments the growth of adaptive technology and the need for accessibility by permitting the creation of limited types of derivative works; providing rights to circumvent technological protection measures; and granting the freedom of import and export of accessible works. Furthermore, the proposed treaty compliments current disability law in the sense that it mirrors the legislative intent to provide a clear and comprehensive mandate for the elimination of discrimination against individuals with disabilities, including discrimination in access to information.

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The Fight for Accessible Formats: Technology as A Catalyst for a World Effort to Improve Accessibility Domestically

Mary Bertlesman*

I. Introduction

We live in a wireless, touch-screen, online world where technology is constantly evolving.[1] Technology is becoming an essential part of everyday life and while 81% of adults without disabilities use the Internet, only 54% of adults with disabilities use the Internet.[2] Despite the arguable lack of access causing this discrepancy, it is this growth in technology that is fostering a positive change and removing barriers for people with disabilities.[3] Technology is unlocking a world of ways in which people with disabilities can access previously inaccessible materials. Braille translators, screen readers, speech synthesizers, TTYs, and other adaptive technologies are providing people with disabilities more access to the world around us.

As our knowledge-based world goes through rapid technological developments, access to copyrighted work is becoming essential to everyday life.[4] Consequently, access to

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[1] THE AMERICAN ASSOCIATION OF PEOPLE WITH DISABILITIES, *Technology,* http://www.aapd.com/what-we-do/technology/ (last visited Mar. 10, 2012).

[2] *Id.*

[3] Sheryl Burgstahler, *Working Together: People with Disabilities and Computer Technology,* DO-IT, http://www.washington.edu/doit/Brochures/PDF/wtcomp.pdf (last visited Mar. 10, 2012).

[4] Margot E. Kaminski & Shlomit Yanisky-Ravid, *Addressing the Proposed WIPO International Instrument on Limitations and Exceptions for Persons with Print Disabilities: Recommendation or Mandatory Treaty* (Yale Information Society Project, Working Paper, 2011), at 7.

copyrighted work is also essential to full participation in society.[5] The United States has created several federal laws to further the goal of full participation and to protect the rights of people with disabilities. The Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Individuals with Disabilities Education Act of 1990, and the Copyright Act are among several laws that have been enacted in the United States prohibiting discrimination on the basis of disability and promoting equality of all people with disabilities. These laws, particularly, the US copyright laws, have their limitations.[6] The United States copyright laws often prevent persons with print and other reading impairments from obtaining accessible versions of copyrighted works.[7]

The World Intellectual Property Organization (WIPO) is currently addressing this problem on a global scale.[8] According to a study done by WIPO, the licensing system for making written works accessible is inadequate and insufficient.[9] Despite protections provided to persons with print disabilities under international and domestic laws, they are frequently denied access to educational material, literature, entertainment, and the free flow of ideas, which allow for full participation in society.[10]

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[5] Kaminski, *supra* note 4, at 7.

[6] *Id.* at 8; U.N. World Intellectual Property Organization (WIPO), Standing Committee on Copyright and Related Rights (SCCR), Study on Copyright Limitations and Exceptions for the Visually Impaired, 38, WIPO Doc. SCCR/15/7 (Feb. 20, 2007) (prepared by Judith Sullivan) (hereinafter Fifteenth Session).

[7] Kaminski, supra note 4, at 8; Fifteenth Session, *supra* note 6, at 38.

[8] *Id.* at 3.

[9] *Id.*

[10] *Id.*

WIPO is now working with the United Nations to propose an international instrument to enable accessibility for persons with print disabilities.[11] The proposed instrument will provide specific limitations and exceptions to domestic copyright laws.[12] In particular, this instrument will make it legal for individuals with print disabilities and certain organizations to obtain accessible versions of copyrighted works in countries which sign the treaty. As a result, accessible books to be available to be sent internationally without permission from publishers. It also will prohibit contracts with publishers from undermining copyright exceptions for readers with disabilities.[13]

To better appreciate the need for an instrument like the one proposed by WIPO, it is important to understand the history of United States copyright law as well as the relationship between US disability rights laws and copyright law.

II. The Copyright Clause of the United States Constitution

The drafters of the United States Constitution recognized the need for progress in science and the arts to create a prosperous and enduring nation. As such, they created the Copyright Clause of the Constitution. Article I, Section 8, Clause 8 of the United States Constitution states: "The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[14] With the power given to it by the Copyright

[11] Kaminski, supra note 4, at 3. The Standing Committee on Copyright and Related Rights (SCCR) agreed at its twenty second session in June, 2011.

[12] WIPO Secretariat, *Study on Copyright Limitations and Exceptions for the Visually Impaired* 3, (WIPO Doc. SCCR/22/8, Working Paper No. 38, 2011) (hereinafter Twenty-Second Session).

[13] See Twenty-Second Session, *supra* note 12.

[14] U.S. CONST. art. I, § 8, cl. 8.

Clause, Congress enacted the first federal copyright statute in 1970.[15] Since then, the legislative scheme has been amended many times.[16] The most recent version of the US Copyright Act was adopted in 1976 and is codified in Title 17 of the United States Code.[17]

III. The Copyright Act of 1976

The Copyright Act of 1976 protects the original works of authorship fixed in a tangible medium of expression, including books, music, sound recordings, and audiovisual works.[18] The author of a work has the exclusive right to reproduce, prepare derivate works, distribute, publically perform, publically display, and digitally transmit audio.[19] Furthermore, the author of a work has the right to authorize these exclusive rights.[20] However, there are certain limitations and exceptions to these exclusive rights. The tension between the interests of the author and the users is the foundation of these limitations and exceptions.[21]

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[15] MARY LAFRANCE, COPYRIGHT LAW IN A NUTSHELL 1 (West 2d ed., 2008).

[16] *Id.*

[17] *Id.*

[18] ADVISORY COMM'N ON ACCESSIBLE INSTRUCTION MATERIALS, DRAFT REPORT FROM TASK FORCE 4 (LEGAL), (Jan 7, 2011); Copyright Act of 1976, 17 U.S.C. § 102 (1976).

[19] 17 U.S.C. § 106 (2002).

[20] *Id.*

[21] Kaminski, *supra* note 4, at 6.

A. *The Fair Use Exception*

The fair use exception is the most significant limitation on a copyright holder's exclusive rights.[22] This doctrine prevents "rigid application of the copyright statute when, on occasion, it would stifle the very creativity which that law is designed to foster."[23] It exempts from liability certain moderate uses of a copyrighted work when those uses will not undermine the economic interests of the copyright owner.[24] The Fair Use exception involves the balancing of four factors: (1) the purpose and character of the use; (2) nature of the copyrighted work; (3) amount and substantiality of the portion used; and (4) the effect upon the market of the copyrighted work.[25] Because Section 107 of the law specifies that the analysis of fair use "shall include" the four factors, there is an indication that other factors may also be considered.[26] For example, some courts have considered the bad faith of the defendant, the industry custom, and the public interest of the defendant's activities.[27] Although the court may consider other factors, the term "shall" indicates that all four of the listed factors must be addressed.[28]

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[22] UNITED STATES COPYRIGHT OFFICE, *Fair Use*, http://www.copyright.gov/fls/fl102.html (last visited Mar. 10, 2012).

[23] ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF COPYRIGHT LAW 432 (West 2010).

[24] *Id.*

[25] 17 U.S.C. § 107 (1992).

[26] SCHECHTER, *supra* note 23, at 437.

[27] *Id.*

[28] *Id.*

i. The Purpose and Character of Use

The first of the fair use factors concentrates on the "purpose and character" of the defendant's use.[29] This focus mirrors the theme of Section 107's preamble, which lists several types of uses that the statutory drafters considered fair use.[30] Fair uses listed in the preamble includes: (1) criticism; (2) comment; (3) news reporting; (4) teaching; (5) scholarship; and (6) research.[31] However, just because a defendant purports to be engaged in one of these "protected" activities does not mean that a defendant will prevail on a claim of fair use.[32] For example, a teacher who makes duplicate copies of a textbook and distributes them to his entire class will not escape liability as a result of the fair use exception.[33] In addition to the uses listed in the preamble, a work that is significantly altered, used for a different purpose, and appeals to a different audience, is likely to be considered fair use.[34] This situation often referred to as transformative use.[35]

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[29] SCHECHTER, *supra* note 23, at 437.

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] SCHECHTER, *supra* note 23, at 437.

[34] NOLO LAW FOR ALL, *The 'Fair Use' Rule: When Use of Copyrighted Material is Acceptable*, http://www.nolo.com/legal-encyclopedia/fair-use-rule-copyright-material-30100.html (last visited Mar. 10, 2012).

[35] SCHECHTER, *supra* note 23, at 442.

As the statutory language indicates, the issue of commercial use is also important. Generally, courts are less willing to extend the fair use exception when the use is commercial in nature.[36]

ii. Nature of the Copyrighted Work

The second factor courts consider in granting exceptions to the protections of the copyright law is the nature of the copyrighted work. Typically, highly creative works are afforded the greatest degree of protection.[37] Courts, therefore, are less likely to extend the fair use exception when a fictional copyrighted work is in question. "The law generally recognizes a greater need to disseminate factual works than works of fiction or fantasy."[38] However, a fictional or creative work may not preclude a finding of fair use when the copying is deemed transformative under the first factor.[39]

Furthermore, the unpublished nature of a copyrighted work may affect the court's use of this exception. Typically, if the copyrighted work is unpublished, it is less likely to be considered fair use. The Court in *Harper & Row, Publishers, Inc. v. Nation Enterprises* concluded the following: "the author's right to control the first public appearance of his expression weighs against such use of the work before its release."[40]

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[36] Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 562 (1985) ("The fact that a publication was commercial as opposed to nonprofit is a separate factor that tends to weigh against a finding of fair use.").

[37] SCHECHTER, *supra* note 23, at 447.

[38] *Harper & Row*, 471 U.S. at 563.

[39] *See* Blanch v. Koons, 467 F.3d 244, 257 (2d Cir. 2006) ("[T]he second factor may be of limited usefulness where the creative work of art is being used for a transformative purpose." (quoting Bill Graham Archives v. Dorling Kindersley Ltd., 448 F.3d 605, 612 (2d Cir. 2006))).

[40] *Harper & Row*, 471 U.S. at 564.

iii. Amount and Substantiality of the Portion Used

The third factor lends itself to the logic that the more a work is copied, the more likely it infringes upon copyright protections. As a result, extensive takings are less likely to be ruled as fair use than a single borrowing.[41] While this analysis is closely tied to considerations regarding the first factor, the determination of the amount and substantiality of the portion used in relation to the copyrighted work as a whole involves not only a quantitative analysis, but also a qualitative analysis.[42] In other words, the third factor focuses on the quantity of the material taken and the significance of that material to the plaintiff's work as a whole.

iv. The Effect Upon the Market of the Copyrighted Work

In *Harper & Row*, the Supreme Court explained that the forth factor is "undoubtedly the single most important element of fair use."[43] This factor considers the effect of the defendant's use on the potential market for the plaintiff's work.[44] This factor assumes that if the defendant's conduct causes a significant number of people to refrain from paying for the plaintiff's work, the incentive to be creative would be reduced. Such weighing of potential effects must focus on both the particular effects of the defendant's conduct, and the market implications if the defendant's conduct were to become widely engaged by others.[45]

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[41] SCHECHTER, *supra* note 23, at 449.

[42] *Id.* at 449-50

[43] *Harper & Row*, 471 U.S. at 565

[44] SCHECHTER, *supra* note 23, at 451.

[45] *Id.*

B. *The Chafee Exception*

In addition to the fair use exception, the "Chafee exception" is another limitation on an author's exclusive rights. The Chafee Amendment to the Copyright Act of 1976 was introduced in 1996 to permit nonprofits and governmental agencies to provide alternative accessible copies of previously published nondramatic literary works in specialized formats. This amendment is particularly important when considering the rights of persons with disabilities, especially the blind. The "Chafee exception" provides that "… it is not an infringement of copyright for an authorized entity to reproduce or to distribute copies or phonorecords of a previously published, nondramatic literary work if such copies or phonorecords are reproduced or distributed in specialized formats exclusively for use by blind or other persons with disabilities."[46] An authorized entity "means a nonprofit organization or a governmental agency that has a primary mission to provide specialized services relating to training, education, or adaptive reading or information access needs of blind or other persons with disabilities."[47]

While this exception does provide persons with disabilities some rights, it applies only to reproduction and distribution rights.[48] Therefore, the exception does not allow a covered entity to prepare a derivative work, such as an audio book recording. Nevertheless, the "Chafee exception" has provided a remedy for organizations devoted to supplying accessible materials. Prior to the "Chafee exception," organizations would need to get permission from individual copyright owners, which proved to be a slow and laborious

[46] 17 U.S.C. § 121 (2004).

[47] 17 USC § 121(d)(1) (2004).

[48] 17 USC § 121(a) (2004).

process filled with significant administrative complexities.[49] While this exception has provided a remedy, there is a caveat – only authorized entities have been provided this remedy.

IV. The Individual with Disabilities Education Act

The Individual with Disabilities Education Act (IDEA) was enacted to govern how special education and related services are provided for children with disabilities. The IDEA of 2004 included provisions related to the "Chafee exception." In particular, the 2004 IDEA requires the Chafee Amendment to cover instruction materials provided to the visually impaired.[50] Furthermore, the IDEA of 2004 created a National Instructional Materials Accessibility Standard (NIMAS).[51] The NIMAS required educational agencies to create accessible versions of textbooks as well as an XML-based format that would allow for the easy creation of derivative works.[52]

V. The Digital Millennium Copyright Act of 1998

The Internet has been a driving force in helping people share intellectual works.[53] The problem, however, is that many people share such works without regard for the

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[49] ADVISORY COMM'N ON ACCESSIBLE INSTRUCTION MATERIALS, DRAFT REPORT FROM TASK FORCE 4 (LEGAL), 6 (Jan 7, 2011).

[50] WIPO, *Best Practices*, http://www.visionip.org/vip_resources/en/best_practices/us.html (last visited Mar.10, 2012).

[51] *Id.*

[52] *Id*.

[53] Iheanyi Samuel Nwankwo, *Proposed WIPO Treaty for Improved Access for Blind, Visually Impaired, and Other Reading Disabled Persons and Its Compatibility with TRIPS Three-Step Test and EU Copyright Law*, JIPITEC, http://www.jipitec.eu/issues/jipitec-2-3-2011/3175/nwankwo.pdf (last visited Mar. 10, 2012).

requirements of copyright law. This situation has brought about many challenges to authors and has resulted in greater copyright protections.

The Digital Millennium Copyright Act (DMCA) was enacted to implement two 1996 treaties of WIPO.[54] The DMCA criminalizes production and dissemination of technology, devices, or services intended to circumvent measures that control access to copyrighted works.[55] The juxtaposition of the Chafee Amendment with the DMCA—one permitting reproduction in specialized formats, such as text-to-speech, but the other prohibiting the use of certain technology, such as synthetic-voice screen readers, to make or use those formats – has created a legal ambiguity.[56] The ability to exercise current limitations and exceptions to copyright protections, including those provided by the fair use doctrine and the Chafee exception, is proving more difficult as authors focus on ways to protect their ownership rights against unauthorized uses made available through technological innovations.[57]

While new copyright laws have focused on the conflicts between copyright owners and those who pirate their work, persons with visual impairments have been the unintended victims of this conflict.[58]

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[54] U.S. COPYRIGHT OFFICE, *The Digital Millennium Copyright Act of 1998*, http://www.copyright.gov/legislation/dmca.pdf (last visited Mar. 10, 2012).

[55] AMERICAN LIBRARY ASSOCIATION, *DMCA: The Digital Millennium Copyright Act*, http://www.ala.org/advocacy/copyright/dmca (last visited Mar. 10, 2012).

[56] Elsa F. Kramer, *Digital Rights Management: Pitfalls and Possibilities for People with* Disabilities, THE JOURNAL OF ELECTRONIC PUBLISHING *available at* http://quod.lib.umich.edu/j/jep/3336451.0010.106?rgn=main;view=fulltext (last visited Mar. 10, 2012); THE COLUMBIA GUIDE TO DIGITAL PUBLISHING 325-68 (William E. Kasdorf ed., Columbia University Press 2003).

[57] Kramer, *supra* note 56.

[58] Nwankwo, *supra* note 53.

VI. Current Events Reflect Tension Between Accessibility and Copyright

A. *Authors Guild v. Google*

In 2004, Google announced that it had entered into agreements with several major research libraries to digitally duplicate books and other writings.[59] In July of 2011, Google scanned more than 12 million books and delivered digital copies to the participating libraries, created an electronic database of books, and made text available for online searching. [60] Millions of the scanned books, however, were still protected by copyright.[61] As a result, authors and publishers brought a class action suit against Google for copyright infringement. While the plaintiffs sought both damages and injunctive relief, Google claimed that its actions were exempt from copyright infringement through the fair use exception.[62]

In its claim of fair use, Google argued the numerous benefits of increased accessibility. Google argued that libraries, schools, researchers, and disadvantaged populations would gain access to far more books. Through digitization, conversion of books to Braille and audio formats would be facilitated. Furthermore, older books—particularly out-of-print books – would be preserved. In its defense, Google also argued that the reproductions would not undermine the economic interests of copyright owners and such

[59] Authors Guild v. Google, Inc., 770 F. Supp. 2d 666, 670 (S.D.N.Y. 2011); *See generally* Emily Anne Proskine, *Google's Technicolor Dreamcoat: A Copyright Analysis of the Google Book Search Library Project,* 21 Berkeley Tech. L. J. 213, 220–21 (2006) (describing project).

[60] *Authors Guild*, 770 F.2d at 670; Proskine, *supra* note 59.

[61] *Id.* at 670.

[62] *Id.* at 670-71.

reproductions would actually benefit authors by generating new audiences, and thus new sources of income.[63]

The case was eventually settled in October of 2008. Nevertheless, the issues of fair use and the conversion of works to accessible formats through the use of new technologies were not decided.[64]

B. *Authors Guild & Amazon*

Less than a year after the settlement between the Authors Guild and Google, a request was made by the Authors Guild for Amazon to disable its Kindle 2's robotic text-to-speech feature. This feature enabled any book to be read aloud in a synthesized voice.[65] While this feature gave persons with visual impairments access to books they otherwise would not have had, the Authors Guild contended that such a feature would cut the sale of books that were already available in audio formats.[66] To avoid potential litigation, Amazon disabled the feature and yet again the issues of fair use and the conversion of works to accessible formats through the use of new technologies were left unresolved.[67]

Cases like those between the Authors Guild, Google, and Amazon soon gained international attention. While current domestic law has created ambiguities regarding which texts are covered by copyright laws and for what purpose, it also has limited the cross-border

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[63] *Authors Guild*, 770 F.2d at 670.

[64] *Id.* at 670-71.

[65] Nwankwo, *supra* note 53.

[66] *Id.*

[67] *Authors Guild*, 770 F.2d at 671.

transfer of accessible formats.[68] It is in this light that an international treaty, which can clarify current domestic law and create uniformity across borders, is necessary.

VII. The Need for a Treaty

The controversy between the economic interests of authors to enjoy the fruits of their labor and the interest of the State to provide the public with access to literary works for the advancement of knowledge, appears to remain unsolved despite the exceptions provided by the fair use and Chafee doctrines.[69] This battle also exists on a global scale and the recent attempt to internationally harmonize the limitations and exceptions for the benefit of people with vision impairments has caused this controversy to resurface.[70]

Currently, there is no provision in any international treaty relating to intellectual property that specifically provides for exceptions or limitations to copyright for the benefit of those who are visually impaired.[71] While the Berne Convention, the Agreement of Trade Aspects of Intellectual Property Rights, and the WIPO Copyright Treaty allow states to include in their intellectual property law exceptions or limitations to copyright (that do no conflict with the interests of right holders), accessibility for people with visual impairments has not improved.[72] WIPO is taking steps to address this problem and has commissioned

[68] Nwankwo, *supra* note 53.

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] Nwankwo, *supra* note 53; Fifteenth Session, *supra* note 6.

several studies focusing on the problems that visually impaired people face in regards to access of intellectual works.[73]

The United Nations is, at the same time, working to change the attitudes and approaches towards persons with disabilities. The Convention on the Rights of Persons with Disabilities (CRPD) was adopted on December 13, 2006. Signed by the United States in 2009 (but not yet ratified), the CRPD affirms the right of all persons with disabilities to dignity, autonomy, freedom and nondiscrimination.[74] Further, Article 30 of the CRPD specifically obliges Member States to take appropriate measures to ensure that copyrighted law does not constitute and unreasonable or discriminatory barrier to access to cultural materials by persons with disabilities.[75]

Despite these international and domestic efforts, people with vision impairments are still challenged to gain access to adaptive formats of literary works. It remains a challenge technically, legally, and economically.[76] Studies indicate that only five percent of all published books are available in accessible formats.[77] Furthermore, people with visual impairments can only have access to literary works if they exist in adaptive formats, such as Braille, audio recording, audio-visual, or digital-compatible formats.[78] The WIPO Study on Copyright Limitations and Exceptions for the Visually Impaired observed that the shortage

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[73] Nwankwo, *supra* note 53, at 205.

[74] *See* Convention on the Rights of Persons with Disabilities, G.A. Res. 61/106, at 25(d), U.N. Doc. A/RES/61/106 (Dec. 13, 2006).

[75] Kaminski, *supra* note 4, at 8.

[76] Fifteenth Session, *supra* note 6.

[77] *Id.*

[78] Nwankwo, *supra* note 53, at 205.

of access to copyrighted works is created by "difficulties in reaching licensing agreements" for accessible copies.[79] Moreover, the high cost of converting works into accessible formats and the restriction on the importation of accessible formats from cheaper sources has also harmfully affect persons with visual impairments from accessing information that would benefit them.[80] WIPO has acknowledged this problem by proposing a treaty to provide specific limitations and exceptions to copyright.[81]

VIII. History of the WIPO Copyright Treaty for Improved Access

A. *The Eighteenth Session*

At the eighteenth session of the WIPO Standing Committee on Copyright and Relates Rights (WIPO Standing Committee), Brazil, Ecuador, and Paraguay, on behalf of the World Blind Union, proposed a treating aimed a improving to copyrighted works for those who have visual impairments.[82] The proposed treaty addresses three important issues facing those with visual impairments: (1) the creation of limited types of derivative works; (2) rights to circumvent technological protection measures; and (3) the freedom of import and export of

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[79] Fifteenth Session, *supra* note 6.

[80] Nwankwo, *supra* note 53, at 205; KNOWLEDGE ECOLOGY INTERNATIONAL, *Background and Update on Negotiations for a WIPO Copyright Treaty for Persons Who Are Blind or Have Other Disabilities*, http://www.keionline.org/node/1089 (last visited Mar.11, 2012). See also, *International Committee of the Universal Copyright Convention: Copyright Problems Raised by the Access by Handicapped Persons to Protected Works* (1985), *available at* http://unesdoc.unesco.org/images/0006/000651/065169eb.pdf.

[81] Twenty-Second Session, *supra* note 12.

[82] WIPO, Standing Comm. on Copyright and Related Rights, Proposal by Brazil, Ecuador and Paraguay, Relating to Limitations and Exceptions: Treaty Proposed by the World Blind Union (WBU), Annex 1 pmbl., at 2, SCCR/18/5 (May 25, 2009) [hereinafter WBU Proposed Treaty]; Patrick Hely, *A Model Copyright Exemption to Serve the Visually Impaired: An Alternative to the Treaty Proposals Before WIPO*, 43 Vand. J. Transnat'l L. 1369, 1393 (2010).

accessible works.[83] The scope of these exceptions would be limited to personal reproduction by the visually impaired individual, a nonprofit organization, or by a for-profit organization on a nonprofit basis or with "adequate remuneration to copyright owners."[84] Like other limitations on exclusive rights, such as the United States' Chafee exception, a party meeting one of these qualifications would not need the author's permission. Furthermore, this treaty would grant the right of distribution and the right to create additional copies.[85]

B. *The Twentieth Session*

At the twentieth session of the WIPO Standing Committee, the European Union, the African Group, and the United States proposed three additional instruments.[86] While the solutions offered by the United States and the European Union arguably narrowed the scope of the exceptions provided by the first proposed treaty, the African treaty expanded scope of the debate.[87] The African treaty went as far as to include "unauthorized and unrecompensed reproduction for research purposes, educational and research institutions, libraries, and archives."[88] Moreover, the African proposal expanded the class of beneficiaries, including persons with "a physical, mental, sensory, or cognitive incapacity."[89]

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[83] Hely, *supra* note 82, at 1393.

[84] *Id.*

[85] *Id.*

[86] *Id.* at 1395.

[87] Hely, *supra* note 82, at 1395.

[88] *Id.*

[89] WIPO, Standing Comm. on Copyright and Related Rights, Draft WIPO Treaty on Exceptions and Limitations for the Disabled, Educational and Research Institutions, Libraries and Archive

While the African proposal aimed to increase the ability to reproduce, and thus increase accessibility, the United States' proposal limited trade to that of Braille texts and required the establishment of "trusted intermediaries" for trade in other accessible formats.[90] Trusted intermediaries include governmental agencies and nonprofit organizations dedicated to assisting the visually impaired.[91] In addition, the United States' proposal limited imports and exports to published works that are not domestically available in the accessible format concerned.[92]

The European Union's proposal mirrored many ideas expressed in the other proposals. However, it was the only proposal that encouraged programs aimed at seeking affordable technological solutions. [93]

C. *Twenty-Second Session*

The twenty-second session continued to focus on the issue of blind and visually impaired people's access to copyrighted material. However, the focus also was placed on the limitations and exceptions for the benefit of other "disabled persons."[94] Brazil, Mexico, the

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Centers, SCCR/20/11 (June 15, 2010) [hereinafter African Proposed Treaty] (offering a second proposed treaty presented by the African Group) art. 21(a), at 10; Hely, *supra* note 82, at 1395.

[90] WIPO, Standing Comm. on Copyright and Related Rights, Draft Consensus Instrument, SCCR/20/10 (June 10, 2010) [hereinafter U.S. Consensus] (proposing a consensus instrument presented by the United States) art 2-3, at 3-4; Hely, *supra* note 82, at 1396.

[91] Hely, *supra* note 82, at 1396.

[92] *Id.*

[93] *Id.*

[94] INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY E-NEWS, *WIPO Standing Committee on Copyright and Related* Rights, https://www.aippi.org/enews/2011/edition20/WIPO.html (last visited Mar. 11, 2012).

United States, and the European Union submitted an unofficial joint text.[95] Whereas the joint text was agreed upon, the legal nature of the instrument was not settled – the European Union and the United States prefer a nonbinding instrument while Brazil, India, and the African Group prefer a binding convention.[96]

The joint text, also referred to as the "non-paper," was the topic of much debate – the result – a chair proposal. This proposal is now the "basis for future text-based work."[97]

D. *Twenty-Third Session*

The twenty-third session provided the library community an unprecedented opportunity to share its knowledge and experience concerning issues related to copyright for libraries.[98] Member States also had the opportunity to comment on the Chair's proposal. These comments were incorporated into a new working instrument to be used as the basis for work at the twenty-fourth session, sometime in 2012.[99]

IX. Current Domestic Exceptions Compared to Proposed Treaty Exceptions

As previously mentioned, the twenty-second session of the Standing Committee on Copyright and Related Human Rights focused on the limitations and exceptions on accessible

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[95] INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY E-NEWS, *WIPO Standing Committee on Copyright and Related* Rights, https://www.aippi.org/enews/2011/edition20/WIPO.html (last visited Mar. 11, 2012).

[96] *Id.*

[97] Twenty-Second Session, *supra* note 12.

[98] DISTRICT DISPATCH, *Copyright Limitations for Print Disabled Discussed at WIPO*, http://www.districtdispatch.org/2011/12/copyright-limitations-for-print-disabled-discussed-at-wipo/ (last visited Mar. 11, 2012).

[99] *Id.*

formats. In the *National Law Exceptions on Accessible Format Copies* section, the proposed treaty requires Member States to "… provide in its national copyright law for an exception or limitation to the right of reproduction, the right of distribution and the right of making available to the public, to facilitate the availability of works in accessible formats for beneficiary persons …."[100] This section also suggests that the national exception cover "accessible format copy … which may include any means needed to navigate information in the accessible format.[101]" This is significant because the phrase "accessible format" would include any work that is accessible – even if it could be used by the general public and not limited to use by people with disabilities.[102]

This exception differs from the Chaffee Exception, which only covers "specialized formats" – formats only intended for use by people with disabilities.[103] Historically, these formats have included large print and Braille. While there are numerous interpretations of "specialized formats," the general interpretation of "specialized formats" has resulted in the exclusion of many modern formats, such as electronic books.

The lack of explicitly defining the term "specialized format" has resulted in confusion. This confusion is evident in the different practices by nonprofits in the United States. For example, the National Library Service for the Blind and Physically Handicapped loans books

[100] Twenty-Second Session, *supra* note 12.

[101] *Id.*

[102] *Id.*

[103] 17 U.S.C. § 121 (2004).

in a "specialized format" that are unusable by the general public.[104] Bookshare, on the other hand, provides digital formats via the Internet that could be easily used by the general public, if security controls failed.[105] Despite the fact that these digital formats can be accessed by the general public at more ease than formats provided by the National Library Service for the Blind and Physically Handicapped, Bookshare is under the impression that these formats are "specialized formats." [106]

This debate over what qualifies as a "specialized format" has not been resolved. In 2011, the Advisory Commission on Accessible Instructional Materials in Post Secondary Education for Students with Disabilities tried to provide some guidance with a statutory definition. According to the Advisory Commission, "braille, audio, or digital text which is exclusively for use by blind or other person's with disabilities; and with respect to print instructional materials, includes large print formats when such materials are distributed exclusively for use by blind or other persons with disabilities."[107] This definition makes clear that there are two parts of the definition up for debate: (1) the nature of the format and (2) the scope of who is covered by the law. While the Advisory Commission has come to the conclusion that there should be limitations on those covered, as prescribed in Section 121 of

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[104] NATIONAL LIBRARY SERVICE, *NLS: Frequently Asked Questions: Digital Talking Books*, http://www.loc.gov/nls/dtbfaq.html (last visited Mar. 11, 2012).

[105] BOOKSHARE, *Legal Information*, http://www.bookshare.org/_/aboutUs/legalInformation (last visited Mar. 11, 2012); BOOKSHARE, *International Membership*, http://www.bookshare.org/_/membership/international (last visited Mar. 11, 2012).

[106] BOOKSHARE, *International Membership*, http://www.bookshare.org/_/membership/international (last visited Mar. 11, 2012).

[107] U.S. DEPARTMENT OF EDUCATION, *Advisory Commission on Accessible Instructional Materials in Postsecondary Education for Students with Disabilities*, http://www2.ed.gov/about/bdscomm/list/aim/publications.html (last visited Mar. 11, 2012).

the Chafee Amendment, a Treaty could expand on these limitations by changing national copyright laws.

Despite the Advisory Commission's conclusion, the Commission made the following recommendation:

> Congress should review the scope, effectiveness and function of the Copyright Act as amended to determine whether it or any of its key component elements, as well as its implementation through applicable standards, need to be updated to adequately address the needs of individuals with print disabilities, including those enrolled in postsecondary education.

X. Importance of Treaty in Regards to Digital Rights Management

In addition to the issues related to the scope of individuals covered by current domestic copyright exceptions, the proposed Treaty addresses current digital rights management (DRM) issues. DRM is a class of access control technologies that are used to protect the copyrights of electronic media.[108] DRM is important to publishers of electronic media because it helps ensure they will receive the appropriate revenue for their products.[109] DRM furthers the publisher's ability to protect, monitor, track, and control the trade of digital media, thus limiting the illegal proliferation of copyrighted works.[110]

DRM poses accessibility issues for persons with disabilities because it can interfere with ability of screen readers and other text to speech software to operate.[111] While DRM is technology can be circumvented through hacking measures or through anti-encryption

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[108] TECHTERMS.COM, *Digital Rights Management*, http://www.techterms.com/definition/drm (last visited Mar. 11, 2012).

[109] *Id.*

[110] *Id.*

[111] Kramer, *supra* note 56.

software, those circumvention methods are not always easy or legal to obtain. While the United States allows users to legally circumvent DRM for screen reader access, the rule could arguably be stronger.[112] The proposed Treaty would further the United State's rule to permit circumvention.[113] According to the proposed Treaty:

> In the absence of voluntary measures by rightholders and to the extent that copies of the work in the accessible format are not available commercially at a reasonable price or via authorized entities, Member States shall take appropriate measure to ensure that beneficiaries of the exception provided by [the] Article [on National Law Exceptions on Accessible Format Copies] have the means of benefiting from that exception when technical protection measures have been applied to the work …[114]

The language places a responsibility for the government to help find a way to circumvent DRM.

XI. Domestic Significance of a Binding International Instrument

The binding nature of the proposed instrument is one of the many issues up for discussion at the next WIPO Standing Committee session. While WIPO traditionally favors binding hard law, such as treaties and conventions, the organization did favor a series of nonbinding "Joint Recommendations" in the area of trademark law.[115] Proponents of hard law argue that enactment as soft law would undermine the ultimate goal of the instrument – to make copyrighted works more accessible to individuals with print disabilities.[116]

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[112] 37 C.F.R. § 201.40.

[113] Twenty-Second Session, *supra* note 12.

[114] *Id.*

[115] Kaminski, *supra* note 4, at 10.

[116] *Id.* at 1.

One way in which a nonbinding instrument would likely undermine the ultimate goal is by becoming dead letter – a likely result of enactment as soft law.[117] More importantly, soft law is less appropriate where there is a consensus, as there is here.[118]

Supporters of hard law argue that there are both normative and structural benefits to hard law.[119] Normatively, Member States are more likely to comply because of historical norms of compliance with hard law.[120] Structurally, Member States are required to implement hard law.[121] This not only brings domestic law into compliance with hard law, but it also "increases the number of actors encouraging states to comply … internally."[122]

XII. Opposition to the Proposed Treaty

During the twenty-second session, the United States expressed the opinion that current copyright exceptions are adequate.[123] Consequently, the United States joined the European Union and the International Publishers Association in opposition to the proposed Treaty. Despite the common resistance to the Treaty, the International Publishers Association has a different reasoning behind their opposition. While the United State's government cited adequacy as their reason, publishers are generally against further copyright limitations and exceptions as part of an effort to maintain and increase control over their

[117] Kaminski, *supra* note 4, at 1.

[118] *Id.*

[119] *Id.* at 12.

[120] *Id.*

[121] Kaminski, *supra* note 4, at 12.

[122] *Id.*

[123] Twenty-Second Session, *supra* note 12.

intellectual property. Furthermore, Publishers exhibit a general resistance to technological developments that likely impede on their ability to control the formats and distribution of such property.

It is no stretch of the imagination to conclude that these publishers largely influenced the United States government in its decision to oppose the proposed Treaty. In 2010 alone publishers generated a net revenue of $27.9 billion.[124] Furthermore, this net revenue was a 5.6% increase since 2008, making it even more likely that the publishing industry's opinion had significant weight; especially in the current economy.[125]

In addition to arguments surrounding the adequacy of current exceptions and limitations, as well as arguments surrounding the economic implications of further exceptions and limitations, many opponents argue that derivative works will likely result from technology permitted by the proposed Treaty. For example, many publishers believe that text to speech technology is an audio work that can be copyrighted, while the proposed Treaty takes the stance that text to speech technology only results in temporary copies – which have no economic value and are thus not covered by copyright law.[126] Current U.S. copyright law seems to support the stance taken by the proposed Treaty. Under U.S. copyright law, text to speech creates a temporary, transient work in which a copy does not exist for copyright purposes.[127]

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[124] Julie Bosman, *Publishing Gives Hints of Revival, Data Show*, N.Y. TIMES, Aug. 9, 2011, *available at* http://www.nytimes.com/2011/08/09/books/survey-shows-publishing-expanded-since-2008.html (last visited Mar. 11, 2012).

[125] *Id.*

[126] Kramer, *supra* note 56.

[127] 17 U.S.C.A. § 110 (2005).

Despite the argument that audio rights do not exist for text-to-speech, it is more than likely that the multitude of adjustments needed to create a truly accessible work would result in the creation of a derivative work – which is the sole right of the copyright holder.[128]

XIII. Conclusion

While a growth in innovative technology is fostering the removal of barriers for persons with print disabilities, current U.S. copyright laws are making this new accessibility illegal. Protections afforded to persons with disabilities by the American's with Disabilities Act, the Rehabilitation Act, the Individuals with Disabilities Education Act, the Fair Use Exception, and the Chafee Amendment are no adequate. Moreover, copyright laws created to promote progress through education are actually denying person's with print disabilities access to educational materials, literature, and entertainment. The need to provide incentives to authors and publishers has become arguably more important than the fundamental right of equality. This discrimination has become even more evident through recent events involving Google and Amazon.

In recognizing this discrimination, WIPO has proposed a treaty to provide for specific limitations and exceptions to copyright law – something the Berne Convention, the Agreement of Trade Aspects of Intellectual Property Rights, and the WIPO Copyright Treaty have not done. The proposed treaty addresses three important issues facing those with visual impairments: (1) the creation of limited types of derivative works; (2) rights to circumvent technological protection measures; and (3) the freedom of import and export of accessible works.[129] The scope of these exceptions would be limited to personal reproduction by the

[128] 17 U.S.C. § 121 (2004).

[129] Hely, *supra* note 82.

visually impaired individual, a nonprofit organization, or by a for-profit organization on a nonprofit basis or with "adequate remuneration to copyright owners."[130] Like other limitations on exclusive rights, such as the United States' Chafee exception, a party meeting one of these qualifications would not need the author's permission. Furthermore, this treaty would grant the right of distribution and the right to create additional copies.[131]

In addition to the three aforementioned issues of focus, the proposed treaty, if binding, has the ability to provide greater access by providing a model law for countries that do not have current copyright exceptions for accessible works, as well as for countries that do have current exceptions - but which are failing to provide truly accessible works.

As our knowledge-based world goes through rapid technological developments, access to copyrighted work is becoming essential to everyday life and total welfare. Access is essential to full citizenship.

While current copyright laws have arguably fostered discrimination on the basis of disabilities, in particular print disabilities, the ratification of the proposed treaty is a step closer to providing the equality guaranteed to all people with disabilities throughout the world in the 2006 Convention on the Rights of People with Disabilities.

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[130] Hely, *supra* note 82.

[131] *Id.*

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New Frontiers of Reprogenetics: SNP Profile Collection and Banking and the Resulting Duties in Medical Malpractice, Issues in Property Rights of Genetic Materials, and Liabilities in Genetic Privacy

Stephanie Sgambati, J.D.

Abstract

Single nucleotide polymorphisms (SNPs) represent the portions of our genetic makeup where human differ from each other. Mapping an individual's profile creates a DNA fingerprint entirely unique to that individual. The primary purpose for the creation of SNP profiles has been validation of medical techniques used in reproductive medicine that require researchers to be able to definitively determine which embryo makes which baby- thus matching DNA fingerprints from infants to those from embryos. In spite of this seemingly narrow use, the potential value of the information contained in the SNP profile is enormous.

In this paper, I explore how SNP profiles are collected and what it means for their potentiality that they are typically collected under research protocols rather than as standard medical care. I then consider the historical and recent litigation on ownership rights in genetic materials and evaluate how this applies to SNP profiles collected as research data. Next I discuss privacy concerns stemming from the collection of genetic data and analyze the current privacy laws available in terms of their applicability to SNP profiles. I then review the case law on physician liability in connection with genetic diagnosis and assess how the current model cannot work for SNP profiles. Finally, I propose a model for a centralized SNP profile repository that would control and clearly define liabilities, allow patients to manage their own privacy concerns

and allow researchers unparalleled access to SNP data while also allowing patients the benefit of ongoing research on gene/illness analysis. While the current collection and banking of SNP profiles is a liability, we have an opportunity to consider options and create a structure that benefits both researchers and patients.

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New Frontiers of Reprogenetics: SNP Profile Collection and Banking and the Resulting Duties in Medical Malpractice, Issues in Property Rights of Genetic Materials, and Liabilities in Genetic Privacy

Stephanie Sgambati, J.D.[1]

"Science...never solves a problem without creating ten more."

-George Bernard Shaw

Introduction

Over 99% of human DNA is identical between individuals. The places where we differ genetically are called single nucleotide polymorphisms or SNPs. A SNP profile is created by mapping the DNA points where individuals vary and when all of those points mapped, a unique DNA fingerprint is created. DNA fingerprints this highly specific are primarily useful in the context of reproductive medicine research. In order to validate laboratory techniques, embryologists need to be able to track which embryo results in a live-born child. To do this, a single cell can be biopsied from the embryo while it is still growing on culture and its genetically unique SNP profile can be created. A DNA sample can later be collected from a live-born infant, generating another SNP profile that can be compared to SNP profiles of transferred embryos to determine which embryo made the baby. This all may seem simple enough, but SNP

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profiles contain an enormous amount of information, likely representative of the characteristics that make each human different from other humans and potentially substantial information about an individual's predisposition to genetic illness. This information serves no purpose in the context of matching embryos to babies; however, it is an active area of research in its own right. Numerous potential issues and concerns arise in considering how SNP profiles are collected and the information that they contain. In this paper, I seek to explore some of the broad areas of concern related to SNP profile collection and banking.

I first consider the complexities arising from the fact that SNP profiles are largely collected through research protocols but that clinical care and research protocols are highly conflated in reproductive medicine research. I review the various bodies that govern the collection of research data and how they operate. I consider the meaning of informed consent, in both research and genetic counseling contexts. Finally I evaluate the ways in which SNP profiles are unique as compared to other types of research data or genetic testing results particularly in that their meaning and value will continue to evolve as additional information about gene/disease associations becomes available over time.

Next I consider issues arising from questions of ownership of genetic material. I review the jurisprudence of allowance or disallowance of patents on genetically modified products, the processes for isolating genes, cell lines grown from a particular gene mutation, and gene sequences. I consider the public policy arguments for both allowing and not allowing a donor to share in the profits of their cell line as well as the application of these models to SNP profiles.

I then evaluate privacy concerns related to the collection and banking of DNA in the form of SNP profiles. I review the current laws that seek to provide patients with privacy protections and analyze why these laws are insufficient because they never contemplated the potentiality of

SNP profiles and the breadth and depth of information they might contain or how that information might be used. I also consider the reality that DNA can never be truly "deidentified" as the concept is stated in privacy laws, complicating considerations of privacy in relation to SNP data.

I next consider the potential liability for physicians who create SNP profiles using the liability structure in place for other forms of genetic illness counseling and testing. I analyze when a court is willing to extend liability and whether that liability can be extended to third parties. I then argue that this model of liability cannot be applied to the collection and banking of SNP profiles because they require an analysis that is radically different from any other genetic illness or test.

Finally, I propose a model for managing SNP profiles through a centralized repository. I argue that this structure would benefit researchers by giving them a large pool of data and benefit patients by maximizing their access to their SNP profiles as well their access to ongoing research on gene/disease associations. I also consider the potential problems with forming a federally funded SNP repository and explore the ways in which they can be overcome. I elaborate on the structure of this repository and how its use can be customized by patients and how the published research in this area can be overseen by peer review, further enhancing benefits to patients.

I. Overview of Single Nucleotide Polymorphisms: Collection and Use

There are 3.3 billion base pairs in the human genome and variation between individual humans occurs at approximately 10 million sites, known as single nucleotide polymorphisms (SNPs). Approximately 1-2 million sites are highly polymorphic, meaning that there is a high degree of variability between individuals at these sites. These highly variable SNPs have been identified to occur on average approximately once every 1,000 base pairs and are present on all

chromosomes. A recently validated technique involving whole genomic amplification followed by SNP microarray analysis allows for DNA fingerprinting from a couple of cells.[2] Mapping of the presence and nature of these SNPs allows for the creation of a SNP profile, containing approximately 980,000 SNPs. This profile is unique to each individual and works like a genetic fingerprint allow for identification just like an actual finger print.[3]

The most common use for SNP profiles this detailed[4] are in reproductive medicine and they serve two purposes. The first is the matching of the DNA of a live born child with DNA collected from an embryo prior to the embryo being transferred back into the uterus.[5] This allows for validation of various research methodologies.[6] The second purpose is a clinical

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[2] Nathan R. Treff et al., *Accurate Single Cell 24 Chromosome Screening Using Whole Genome Amplification and Single Nucleotide Polymorphism Microarray*, 94 FERTILITY & STERILITY 4, (Supp. 2010).

[3] The variation between SNPs creates the genetic code that distinguishes human traits. Traits like height and eye color are coded by many genes in various locations. In contrast, the trait of perfect pitch is coded by 3 genes.

[4] The federal prison system uses SNP profiles as well, but makes genetic matches based on approximately 13 SNPs currently. *See* DNA INITIATIVE, *Combined DNA Index System*, http://www.dna.gov/dna-databases/codis (last visited Feb. 14, 2011). By comparison, a full SNP profile contains approximately 980,000 SNPs.

[5] For this DNA fingerprinting use, the referenced embryos must be created through in vitro fertilization (IVF) so that they exist outside of the uterus for approximately five days after their creation. Oocytes (human eggs) are surgically retrieved and inseminated with sperm to create embryos. The embryos are cultured on medium as they develop. On either their third day of development, when the embryo contains approximately eight cells, or their fifth day of development, when the embryo contains approximately one hundred cells, a single cell is removed from the embryo using a process called embryo biopsy. The DNA contained in that single cell can be amplified to create a SNP profile of each embryo. DNA is obtained from a live born child by collecting a check swab and comparing it to the DNA profile created from the embryos. This allows for the identification of which embryo developed into a live born child.

[6] Many forms of research on the process and efficacy of the genetic testing of embryos require proof that the DNA result from the embryo biopsy is the same DNA as the result from the live

application. In the process of creating SNP profiles, the twenty-four chromosomes present in every human cell can be evaluated for normalcy.[7] Transferring embryos that have been diagnosed as PGD[8]-normal by microarray techniques have lead to established higher pregnancy and delivery rates.[9] This is marked improvement from the lack of improved pregnancy and delivery rates associated with FISH PGD techniques.[10]

There are numerous forms of microarray testing. One is the creation of SNP profiles, as previously discussed. Another is the quantitative polymerase chain reaction (qPCR) microarray, which looks at the parts of the chromosomes that are identical between people in contrast to the SNP array that looks at variation points. The benefit to SNP profiling is that the technique is validated for DNA fingerprinting, making it the standard technique used in research protocols.[11]

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born infant. This allows for a definitive determination of which embryo develops into a live born child.

[7] A normal human cell contains two copies of the first twenty-two chromosomes. The twenty-third pair are the sex chromosomes and are generally evaluated individually. SNP analysis provides two type of results on an embryo. The first result is copy number, which is the counting of the chromosomes. The second result is genotypic profile, used for the DNA fingerprinting. This genotypic result is not useful clinically as there is insufficient information available to counsel on what phenotype would result from a genotype. Phenotype is the physical manifestation of genetic makeup (genotype).

[8] Pre-Implantation Genetic Diagnosis (PGD) is a generic term that is generally used to indicate any testing done on an embryo prior to its transfer to the uterus. This can include evaluation using fluorescent in situ hybridization (FISH) techniques that involve looking at images of select chromosomes, evaluation for single-gene defects (such as cystic fibrosis), or polymerase change reaction (PCR) microarray techniques.

[9] William B. Schoolcraft, M.D. et al., *Clinical Application of Comprehensive Chromosomal Screening at the Blastocyst Stage*, 94 FERTILITY & STERILITY 5, 1700-06 (2010).

[10] Leeanda Wilton et al., *Preimplantation Aneuploidy Screening Using Comparative Genomic Hybridization or Fluorescence In Situ Hybridization of Embryos From Patients With Recurrent Implantation Failure*, 80 FERTILITY & STERILITY 4, 860-68 (2003).

[11] *See supra* note 2.

The disadvantage to SNP profiling for clinical application is that the genetic copy number results take several weeks to be amplified and evaluated, limiting the use of the technique in a clinical setting where the patient needs the genetic results very quickly. Time is not an issue for research protocols, so this disadvantage in the clinical setting is not a disadvantage in the research setting. The benefit of qPCR microarray is that results are available in a matter of hours so the embryos' chromosomal compliment can be read and they can be transferred fresh. The disadvantage of qPCR microarray is that the technique has not yet been validated for DNA fingerprinting purposes.[12]

The value of SNP profiles for research validation purposes has lead to the accumulation of substantial DNA banks, specifically SNP profile banks, located within reproductive medicine practices. Simultaneously, research into the relationships between SNP profiled genes and numerous diseases has flourished.[13] SNP profiles in private practice currently remain separate from the research of molecular geneticists establishing associations between SNP profiles and diseases for several reasons. First, SNP profiles in reproductive medicine are generally collected under research protocols that are tailored to different needs than those of molecular geneticists seeking to further understanding of gene/disease associations. Second, reproductive endocrinologists are neither molecular biologists nor specialists in all of the areas of medicine on which a SNP profile could offer information. Alone, they cannot adequately counsel patients

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[12] As a result, the qPCR technique cannot be used in the validation of research techniques, when the purpose of performing PGD is not clinically diagnostic, but exclusively for research purposes. This technique will likely be validated for DNA fingerprinting purposes in the foreseeable future, but it has not been validated at the time of this writing. Furthermore, extensive laboratory equipment is needed for qPCR analysis and few centers are able to run the test.

[13] A PubMed search for "SNP associations" yielded 7617 results, with approximately 125 new papers being published each month.

about what their SNP profile might mean. Third, privacy concerns as they relate to holding substantial amounts of genetic information on patients, their children and, in many cases, their frozen embryos, are not well understood. Finally, the physician's potential duty to counsel patients based on their SNP profiles is also poorly understood at this point in time. However, given the prolific production of research on SNP associations and diseases, it is unlikely that patients and doctors will remain unaware of this connection indefinitely. The importance of SNP profiling and the information able to be derived from research on gene/disease associations are only likely to expand in the coming years. For these private practices, the possession of large SNP banks are a potential liability unless a structure can be created to organize and manage both the information that we already have and the information that will be produced on gene/disease associations.

II. Collection of SNP Profiles Through Research Protocols

Since the analysis of an embryo's DNA profile by SNP microarray takes a couple of weeks to complete,[14] the technique is no longer preferred for clinical indications for chromosomal testing.[15] SNP profiling for clinical indications is still used, despite its disadvantages, but there is increasing use of the qPCR technique. However, SNP microarray

[14] *See supra* note 11. Upon the validation of the qPCR microarray technique, the clinical use for SNP microarray was substantially limited. However, without validation of the qPCR microarray technique for DNA fingerprinting purposes, SNP microarray techniques remain in use for research validation requiring DNA fingerprinting.

[15] Clinical indications for genetic testing include a known single gene defect, a known translocation, a history of recurrent miscarriage or advanced maternal age. The qPCR technique can be used to detect some chromosomal translocations, which were previously diagnosed by FISH, however the availability of the test depends on the exact location and size of the translocation in question. Testing for single gene defects still requires the preparation of customized probes to check for the specific mutation(s).

remains the standard for research validation purposes at this time.[16] As such, patients who are consenting to the creation of SNP profiles on themselves and their embryos (both transferred and cryopreserved for potential later use) are often consenting through research protocols and not standard of care consents. Patients participating in IVF research will sign consents for the standard of care IVF process itself[17] as well as a research consent[18] that indicates how their care will differ from standard treatment protocol as a result of participation in the study.[19] Patients gain the benefits of study participation[20] in exchange for contributing data that seeks to validate a technique and the genetic information needed for that validation.[21] However, a patient's clinical treatment and research involvement can be deeply intertwined. Although the patient's clinical

[16] *See supra* note 11; *supra* note 13.

[17] This consent packet will include consents to: the IVF processes of ovarian hyperstimulation, oocyte retrieval, culture of embryos and transfer of embryos, ICSI (intracytoplasmic sperm injection) (process which fertilizes the oocytes manually), assisted hatching (process of encouraging a fertilized embryo to divide, either by laser drilling the external shell of the embryo or bathing the embryo in a weak acid solution), and cryopreservation of extra embryos.

[18] This consent will specify when treatment under the research protocol differs from standard treatment as well as detailing the risks and benefits to participation in the research study. The statement that SNP profiles will be collected on both partners and all embryos as a result of study participation is included in this consent. However, due to Institutional Review Board (IRB) requirements that consents be in plain language, "SNP" typically will not appear on the consent and the collection of SNP profiles will be described as "DNA" only.

[19] Research protocols seeking to validate laboratory techniques related to embryos generally do not seek to control the way in which the IVF process is conducted (unlike drug trials, which control drug doses and lengths of time the drug is taken). As such, patients can undergo any form of ovarian hyperstimulation that their doctor sees fit and the research protocol may not affect their treatment until the biopsy or transfer of the embryos (depending on the nature of the research protocol).

[20] Benefits can range from the opportunity to obtain free genetic screening on their embryos to substantial subsidy of the cost of the IVF cycle to medications and subsidy of the IVF cycle.

[21] While this material is used to validate the research technique being studied, it has numerous other potential uses. *See infra* Section IV and Section VI.

care may not dictated by the study protocol itself, all study samples and data are derived during routine clinical care. The complex nature of the entanglement between clinical care and research is brought to bear on many issues stemming from the collection of genetic material from patients including consenting, privacy and ownership of genetic materials.[22]

The collection of all research data is governed broadly by the Code of Federal Regulations Title 45, Part 46,[23] which outlines the guidelines to be used in conducting research on various classifications of "human subjects."[24] These guidelines are then interpreted by Institutional Review Boards (IRBs) located either within large institutions, such as hospitals, or independent review boards that operate for profit and review research proposals for private medical centers that do not have an internal institutional review board. A research proposal must be submitted to an IRB for approval prior to any consenting or data/specimen collection begins. The IRB meets as a group and reviews the research protocol and the related consent forms. Once the proposal is approved, patients can be enrolled and the research project can begin. This review process seeks to provide protections for both the researcher and the participants. Participants are provided with a resource in the event that they believe they are not treated properly and assurance that their research has been evaluated for safety. Researchers are provided with an assurance that their protocol has been reviewed and approved by an impartial third party that affirms the safety and protections afforded to the participants. The basic structure

[22] *See infra* Section III for a discussion of ownership of genetic materials. *See infra* Section IV for a discussion of privacy issues in genetic materials.

[23] 45 C.F.R. § 46 (2005).

[24] *Id.* (providing for different regulations of adults, children, pregnant women and prisoners).

of this process is the same for various forms of research, from the collection of survey data to the collection of DNA-profiled specimens.

Data collected as part of a research protocol may or may not become a part of a patient's medical record.[25] In many cases, information gathered under a research protocol is deidentified to the researcher to maintain blindness and the integrity of the research findings.[26] While this standard is strictly adhered to in the collection of survey data, when the participant's clinical care is affected by their participation in a research protocol, the situation becomes more complicated.[27] The copy number analysis, which indicates how many copies of each chromosome were documented, is typically included in the patient's medical records. However, the genotype analysis, used to develop the DNA fingerprint, is generally not included because it would be meaningless to the patient. A patient could potentially be interested in phenotype information, but SNP genotypes cannot yet be translated into meaningful phenotype analysis. Often, IRB protocols are used to offer treatments that have not yet been validated as effective, but these treatments cannot be validated without testing them on a patient population. Validation of effectiveness is a critical step in getting a treatment or procedure deemed to be a standard of

[25] WESTERN INSTITUTIONAL REVIEW BOARD, *Information for Research Subjects*, http://www.wirb.com/content/research_subjects.aspx (last visited Mar. 19, 2011)(discussing how being a research subject differs from just being a patient, even if medical treatment is being administered).

[26] *Id*.

[27] For example, if a patient with cancer is undergoing experimental treatment, that treatment is most likely approved under an IRB protocol. The patient's treatment will be considered part of his or her medical record though because it is highly relevant to future care and there is no benefit to not including the treatment information in the medical record. SNP profiles are only partially included in a patient's medical record.

care, incorporated into professional guidelines, and covered by health insurance.[28] Insurance companies rely heavily on the guidelines of professional organizations in making determinations of whether or not to cover a particular test, treatment or procedure.[29]

The process of getting a specific test or treatment included in a guideline could be the result of lobbying for its inclusion, as is likely the case with cystic fibrosis.[30] For example, in 1991 the American College of Obstetricians and Gynecologist (ACOG) issued a committee opinion stating the pre-conception screening for cystic fibrosis should be made available to all couples if both partners are of Caucasian, European or Ashkenazi Jewish descent.[31] It could also be the result of validation of a technique previously considered experimental, but proven effective through research. For example, the process of oocyte preservation is considered to be experimental[32] by the American Society for Reproductive Medicine (ASRM). However, several

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[28] *See generally* Katskee v. Blue Cross/Blue Shield of Nebraska, 515 N.W.2d 645, 651-53 (Neb. 1994) (discussing how the determination of whether or not an "illness" exists is made); Bragdon v. Abbott, 524 U.S. 624, 651-52 (1998) (discussing the role of guidelines generated by professional societies).

[29] *Katskee*, 525 N.W.2d at 651-53.

[30] This lobbying effort is currently ongoing with spinal muscular atrophy, a fatal recessive disease, with screenings available and ACOG issuing a committee opinion in 2009 indicating no need for testing without prior family history. ACOG COMMITTEE OPINION NO. 432: SPINAL MUSCULAR ATROPHY (2009). However, many doctors are ordering the testing on patients, perhaps out of fear of litigation, with insurance companies sometimes refusing to pay for the test, which costs thousands of dollars.

[31] AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG), COMMITTEE OPINION NO. 101 (1991) (discussing the current status of cystic fibrosis carrier screening for patients and their partners). Following the release of this guideline, insurance companies increasingly offered coverage for the cost of the screening test. Without a guideline recommending testing or treatment based on validated effectiveness and a cost-benefit analysis that favors the testing or treatment, an insurance company is unlikely to cover the costs.

[32] AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, ESSENTIAL ELEMENTS OF INFORMED CONSENT FOR ELECTIVE OOCYTE CRYOPRESERVATION: A PRACTICE COMMITTEE OPINION (2008)

clinics offer oocyte preservation as an option for women preparing to undergo cancer treatment that would otherwise likely leave them infertile. There is current research seeking to validate the oocyte vitrification process.[33] If this technique is validated, ASRM guidelines may change to indicate the validity of the options and insurance companies may consider offering coverage for the collection and preservation of oocytes for later use.[34] Insurance companies still have considerable discretion in making a determination of whether or when a treatment is medically necessary, but validation is an important and necessary first step.

The collection of SNP profiles originated as a combination of research and clinical treatment in infertility patients, though now it is mostly research-based.[35] Patients seeking IVF treatment will generally seek to participate in research that will subsidize the costs of their treatment. In studies that collect SNP profiles, it is generally a laboratory technique that is seeking to be validated and that validation will require the ability to match a live born infant's DNA to the DNA collected from an embryo. Since the SNP assay is the only technique currently

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(last visited Mar. 27, 2011), http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Essential_elements(1).pdf. The fertility industry is self-regulated in the United States, largely through membership to ASRM and adherence to its guidelines.

[33] *See, e.g.*, CLINICALTRIALS.GOV, *Evaluation of the Impact of Vitrification on the Reproductive Performance and Potential of Human Oocytes*, http://clinicaltrials.gov/ct2/show/NCT01223118?term=oocyte+vitrification&rank=2 (last visited Mar. 27, 2011) (providing information about an ongoing clinical trial that seeks to validate the vitrification process in human eggs).

[34] Currently, oocyte preservation is generally not a covered benefit. As a result, organizations have developed to attempt to meet the financial needs of patients seeking oocyte preservation prior to cancer treatment. These costs are approximately $10,000 including medications. *See* FERTILE HOPE, http://www.fertilehope.org (last visited Mar. 19, 2011).

[35] *See supra* notes 13-15 and accompanying text. The qPCR technique is not the standard process for DNA analysis in a clinical setting

validated for this purpose, it remains the standard methodology.[36] Patients get no direct benefit from the creation of the SNP profile, their only immediate benefit is the reduced cost of an IVF cycle. The SNP profiles take weeks to generate such that whether the IVF cycle resulted in a pregnancy is already known by the time the SNP profile is available, eliminating the patient's benefit in SNP profile collection.

While patients may be emphatically counseled that the SNP profile is for DNA fingerprinting purposes only and the information will not affect their care, medical ethics can potentially complicate this scenario. For example, if a participant has SNP profiles created on two embryos before they are replaced as a part of a research protocol and then the results on those embryos reveal a genetically abnormal, but compatible with life, result such as Down's syndrome on one embryo and a normal result on the other. If the patient has an ongoing pregnancy, there is most likely both a legal and ethical obligation to counsel the patient on the findings so that they can seek further diagnostics and counseling.[37] However, since the information was collected as part of a research protocol that information is not automatically required to become part of the patient's medical record.[38] In this way, research protocols that create SNP profiles are conflated with patients' clinical care.

Although the question of patient access to information collected as part of a research protocol that might be used to make decisions about whether or not to continue a pregnancy has not been litigated, *Hall v. DHMC* suggested that whatever information is available about potential abnormalities in an ongoing pregnancy must be disclosed, even if the diagnosis is not

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[36] *See supra* note 2; *supra* note 11; *supra* note 13.

[37] *See* Hall v. Dartmouth Hitchcock Med. Ctr., 899 A.2d 240 (N.H. 2006).

[38] *See supra* note 24.

definitive.[39] It seems likely that this standard could be imported to a research framework given the gravity of the situation and the seriousness of the decision that must be made, compounded by the limited amount of time that the parent(s) have to make a decision about whether to continue the pregnancy.

In *Hall*, couple had undergone a series of ultrasounds that while consistently producing abnormal results, were never able to provide a diagnosis, and genetic testing via amniocentesis had produced a normal result.[40] The couple continued the pregnancy and testing of both parents and infant immediately following birth demonstrated the presence of a previously unknown balanced translocation in the father and an unbalanced translocation in the child, resulting in a diagnosis of Trisomy 9q.[41] Of particular significance is that in this case, this infant was the first ever reported case of a live born infant with this particular genetic abnormality, giving the treating physicians little reason to believe that this would be the eventual diagnosis.[42] DHMC demonstrated adequate counseling of the abnormalities seen on ultrasound, in spite of not being able to provide a definitive diagnosis from the amniocentesis, and was found not liable for wrongful birth.[43] *Hall* is particularly relevant to SNP profiles because it is representative of the court evaluating and considering a genetic probability risk-ratio in making a determination of

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[39] *Hall*, 899 A.2d at 247.

[40] *Id.* at 242-45.

[41] *Hall*, 899 A.2d at 242-45. Balanced translocations occur when genetic material is exchanged between chromosomes and many individuals are unaware of their diagnosis until they attempt to reproduce and have difficulty. Gametes produces from an individual with a balanced translocation can be unbalanced, meaning they carry uneven amounts of the exchanged information. Unbalanced translocations are generally not compatible with life.

[42] *Id*. at 244-45.

[43] *Id.* at 247.

whether or not a disclosure standard had been met.[44] Given the lack of definitive diagnosis, the ability to counsel the patient was limited to a finite number of disorders that may not appear on an amniocentesis result or the risk of amniocentesis misdiagnosis weighed against the clearly documented abnormalities on ultrasound. Adequate counseling of the patient requires only that the patient understand the limited risk of abnormality at birth based on the genetic testing, even if all other modes of testing conflict with that diagnosis. While this case is not binding outside of New Hampshire, it is likely to be influential on other similar cases due to the lack of precedent in the area.

This situation is further complicated by the future potential of SNP profiles to have predictive value for a host of other illnesses. For example, currently SNP analysis is only used to provide information about the chromosomal compliment via copy number analysis and genotypic analysis.[45] However, as there is increasing scholarship on gene associations with diseases, the potential of genotype SNP analysis to be used to evaluate potential disease risk will become relevant. At some point in the future, a patient may seek their child's SNP profile, collected under a research protocol, in order to have the child's likelihood of developing various illnesses evaluated. In a situation such as this, it is unclear when or if the duty to counsel on the probability of the patient developing a specific illness would come into being. While it is nearly

[44] *Hall*, 899 A.2d at 247.

[45] It is critical to note that a genotypic analysis does not necessarily translate into a phenotypic result. Multiple genotypes can create the same phenotype or a single change in the genotype can create an entirely different phenotype. For example, "grey" and "gray" both have the same meaning (phenotype) but are not made up of the same letters (genotype). However "coat" and "goat" also differ by one letter (genotype), but that change entirely changes the meaning (different phenotypes). Current research on SNP profiles seek to determine which alterations actually effect the phenotype in a meaningful way, rather than just a genotypic change that does not alter the phenotype.

certain that research will continue on SNP profiles and their correlations with illnesses, it is unclear what standard could or would be used in evaluating when the probability is significant enough to counsel a patient.[46]

It is also remains unclear what responsibility the researchers collecting SNP profiles would have to patients. While they create SNP profiles, their sole purpose is DNA fingerprinting and not illness prediction models. Furthermore, reproductive endocrinologists are not geneticists and should not be expected to be able to counsel on the meaning of the presence or absence of genes within a SNP profile. This situation may represent the first time that genetic information is routinely collected and processed apart from an existing structure of genetic testing and counseling as to the clinical implications of the results.

Traditionally, genetic testing is done in concordance with genetic counseling. Genetic counseling involves a genetic counselor taking an oral history of the party or parties and evaluating potential risks of illness based on family history. Genetic counseling is often sought in cases where there is a known family history of illness that is believed to have a strong genetic component or if a prenatal screening test suggests an increased risk of an abnormality.[47] The benefit of genetic counseling is the counselor's ability to suggest screening for certain tests that either fit the symptoms described or are of increased risk in certain ethnic/regional groups. The counselor can then discuss the results, specifically with a consideration of what the likelihood of having an affected child might be.[48] There are far too many genetic illnesses to ever make it

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[46] *See infra* notes 190-94 and accompanying text.

[47] *See* LABCORP, *Genetic Counseling*, https://www.labcorp.com/genetics/genetic_counseling/index.html (last visited Mar. 27, 2011).

[48] *See* LABCORP, *A Basic Guide to Genetic Testing*, https://www.labcorp.com/genetics/basic_guide/index.html (last visited Mar. 19, 2011).

practical to test all people for all possible disorders. As a result, history and ethnic/regional background is used to consider what diseases are more likely to occur, given the individual's self-reported information. SNP profiles cannot be explained to patients in the current genetic counseling model because they are of a different character. They document illness that have combined genetic and environmental factors, which complicates counseling substantially.

Currently, SNP profiles continue to be created in a vacuum, with no meaningful way to translate genotypic information generated by molecular biologists into clinical counseling for patients, but it is highly likely that they will be useful in the future. Furthermore, patients consent to the creation of SNP profiles on themselves and on their embryos as part of research protocols with a limited understanding of the implications of and potential in the creation of SNP profiles. Courts have held that informed consent can occur without the extensive elaboration of complex scientific concepts.[49] The average patient is unaware of how much information is truly contained in a SNP profile and that the value of that information will only increase over time as more research is done on gene associations and polygenomic inherited illnesses. Questions of informed consent, privacy and ownership of genetic material are bound to arise as these cases find their way into court. It would be prudent to consider these issues now and seek to develop a system that will address the concerns raised by the collection of SNP profiles and address them in a way that allows researchers to further science while also providing patients with an informed consent process and access to the benefits of ongoing gene/disease research as it progresses. In

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[49] *See* Bergero v. Univ. of S. California Keck Sch. of Med., 2009 WL 946874 (Cal. Ct. App. Apr. 9, 2009)(Westlaw) (finding that a "mini-medical lecture" is not required for informed consent); Cobbs v. Grant, 502 P.2d 1 (Cal. 1972) (holding that a patient must be provided with all material information that a reasonable patient would want in consenting, but not every possible piece of information related to the procedure in question).

medical research, patients may recognize that their contribution does have the larger goal of furthering scientific study, the incentives associated with research participation, either financial or access to an otherwise unavailable treatment, are often a significant factor in the decision to participate.[50] Many research participants fail to recognize that they are in fact making a contribution to science, which our society values highly, and which has been found to outweigh personal interests in some cases.[51] Moving towards full disclosure with a structure for interpreting and managing the information provided in SNP profiles would benefit all involved parties. Patients would have improved access to their SNP profiles and the research being done on gene/disease associations. Physicians would be assured that patients are getting the information available out of their SNP profiles in the most complete and comprehensive manner possible. And researchers would have access to the largest data pool possible to further scientific inquiry into gene/disease associations.

The research protocols discussed thus far are limited to IRB approved protocols where participants must consent to participation. The C.F.R. recognizes another category of research protocol, known as the exempt protocol, which does not require a subject to consent to be a participant.[52] These protocols typically lack a specific inquiry or timeline and seek to expand knowledge more generally.[53] They frequently involve the use of discard pathology specimens, which are all of the extra materials produced or removed during ordinary medical treatment that

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[50] WESTERN INSTITUTIONAL REVIEW BOARD, *Information for Research Subjects*, http://www.wirb.com/content/research_subjects.aspx (last visited Mar. 19, 2011) (discussing the different reasons why people may participate in research studies).

[51] *See* Moore v. Regents of Univ. of California, 793 P.2d 479 (Cal. 1990).

[52] 45 C.F.R. § 46.101(b) (2005).

[53] *Id*.

would typically be categorized as medical waste.[54] The uses of discarded specimens are narrowly subscribed by IRBs[55] and SNP profiles are not created on discarded specimens. While a full analysis of the benefits and risks of exempt protocols is outside the scope of this note, I raise the issue for two reasons. Firstly, I raise the issue to point out their existence in the larger world of research. Secondly, because it is often the use of discarded specimens that are at issue when questions of property rights in genetic materials come up and the relationship between ownership of genetic materials and the proper consenting of a research subject is critical to the analysis.

III. Property Rights In Genetic Materials

The biotechnology industry has traditionally relied on patent protection over other forms of intellectual property protection for their medical advances, perhaps because while the duration of patent protection is substantially less than copyright or trade secret protection,[56] patent protection is far more absolute.[57] The process of obtaining a patent is substantially more expensive and time consuming than copyright and the requirements are very rigorous.[58] In order

[54] 45 C.F.R. § 46.101(b) (2005).

[55] WESTERN INDEPENDENT REVIEW BOARD, *Exemption Determinations*, http://www.wirb.com/content/wirb_exemption.aspx (last visited Mar. 27, 2011). Some examples of discarded specimens include excess blood not needed to run all of the tests ordered by a doctor or tissue removed from a patient during surgery.

[56] 35 U.S.C. §§ 154, 161, 171 (Westlaw).

[57] 35 U.S.C. § 101 et seq., (Westlaw).

[58] 35 U.S.C. §101-103 (Westlaw).

to obtain a patent, the applicant must show that their invention is novel, non-obvious and useful within the meaning of the patent statute.[59]

Prior to 1980, courts had been largely unwilling to grant patent protection for claimed "inventions" that occur in nature simply because their use is now being exploited.[60] This shifted dramatically in 1980 when the Supreme Court held that a genetically modified organism able to break down crude oil was subject to patent protection.[61] In coming to this conclusion, the Court relied on both practical and public policy considerations.[62] Public policy considerations include an overarching goal of patent law to encourage innovation and reward that investment with a time-limited monopoly as supported by a broad statutory construction.[63] Practically, the Court held that the genetic manipulation of the organism effectively resulted in its "creation" and that fulfilled the *35 U.S.C. § 101* requirements of patentability.[64] This case propelled the protections for the biotechnology industry forward by sanctioning the granting of patents for genetically altered or modified organisms that otherwise occur in nature and had been deemed not patentable prior to *Chakrabarty*.[65]

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[59] 35 U.S.C. §101-103 (Westlaw).

[60] *See generally* Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (all holding that naturally occurring products, phenomena or ideas are not subject to patent protection).

[61] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[62] *Id.* at 308-10.

[63] *Id*. at 308-09.

[64] *Id*. at 309-10.

[65] U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 50 (1987) (hereinafter OTA

In 1985, the Court of Appeals for the Federal Circuit narrowed the potential scope of *Chakrabarty* in holding that a non-obvious use of an otherwise obvious chemical does not inherently make the result or the process patentable.[66] In this case, the patent applicant had taken a common chemical and altered it by a novel process and then put it to use in an non-obvious way.[67] The Court found that a claimed "non-obvious" use of a known chemical does not make the use "non-obvious" within the meaning of *35 U.S.C. § 103*.[68]

In 1991, the Court of Appeals for the Federal Circuit faced the issue of the patentability of genetic material. The Court addressed who was the valid patent owner of the process by which recombinant DNA was created to produce a specific protein used to treat various blood disorders.[69] The plaintiff claimed patent infringement of both the DNA sequence at issue and the process of isolating the sequence and creating the recombinant DNA.[70] The Court focused specifically on the requirement of whether the patented invention had adequate "conception" in the mind of the inventor.[71] Specifically, conception is required for a patent and includes both the idea of the structure as well as the operative method of creating it.[72] In this case, conception

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REPORT); *see also* Rebecca S. Eisenberg, *Genetics and the Law: Patenting the Human Genome*, 39 EMORY L.J. 721, 726-27 (1990).

[66] In re Durden, 763 F.2d 1406 (Fed. Cir. 1985).

[67] *Id.* at 1408.

[68] *Id*. at 1410.

[69] Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1203 (Fed. Cir. 1991).

[70] *Id* at 1204.

[71] *Id*. at 1206.

[72] *Id.* (citing Oka v. Youssefyeh, 849 F.2d 581, 583 (Fed. Cir. 1988*)*); *see also* OTA REPORT, *supra* note 63, at 71.

required both the knowledge of the gene sequence that needed to be isolated as well as the process by which the sequence could be isolated.[73] Most relevant to the analysis at hand is that the Court effectively treated the process of isolating a DNA sequence and the knowledge of the sequence itself to be a single factor for consideration in assessing the validity of the patent.[74] The Court did not consider the possibility that although a DNA sequence alone may not be patentable as it occurs in nature, is obvious and not novel, but that the isolation process may be patentable. By joining the technical sequence with the process, the Court effectively sidestepped the question of patentability of the sequence alone.[75]

Also in 1991, the District Court in Southern California considered the nature of one's right to ownership of their genetic material, but ultimately refused to analyze whether that right was akin to a property right subject to the tort of conversion.[76] The Court explicitly stated that the nature of the right in one's genetic material was a matter of public policy to be decided by the legislature and not the court system.[77]

However, this claim was strikingly different from the holding of the Superior Court of California in *Moore v. Regents of University of California*, decided in 1990.[78] In October of

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[73] OTA REPORT, *supra* note 65, at 71.

[74] Knowledge of a DNA sequence includes the series of coding markers that result in the expression in question as well as on which chromosome the sequence can be found.

[75] Of note, given that the opinion is in the context of a patent infringement suit, the Court may have considered an evaluation of the patentability of genetic sequences to be outside of the case at bar.

[76] *Miles Inc.*, 951 F.2d at 361.

[77] *See id.*

[78] Moore v. Regents of University of California, 51 Cal. 3d 120 (1990).

1976, John Moore first visited UCLA and was diagnosed with hairy-cell leukemia.[79] The defendants collected substantial amounts of blood, bone marrow, and other bodily fluids and they were fully aware after Moore's first surgery that his cells possessed particular characteristics that had the potential to be highly valuable.[80] Moore returned to UCLA medical center numerous times between 1976 and 1983, each time giving blood, serum, bone marrow, skin, and semen samples at the request of his doctors who indicated that these were follow up tests regarding his leukemia when they were in fact the collection of specimens for research purposes.[81] Sometime before 1979, the defendants had established a cell line using Moore's samples and filed for a patent on the cell line in 1981.[82] Moore filed suit claiming conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, unjust enrichment, and eight other related claims.[83] The lower court had dismissed Moore's claims.[84]

Of note, Moore's case was far from the first time that samples collected as part of medical treatment were used for research purposes without disclosure to the patient or their family.[85] The use of specimens collected as part of ordinary medical treatment that would

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[79] *Moore*, 31 Cal. 3d at 125.

[80] *Id.* at 126.

[81] *Id.*

[82] *Id.* at 127.

[83] *Moore*, 31 Cal. 3d at 128.

[84] *Id.*

[85] *See* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS 315-28 (2010).

otherwise be discarded as medical waste are commonly used for research purposes.[86] The most frequently used cell line in the world, known as the HeLa cell line, was derived from Henrietta Lacks in 1951 after an operation to treat her cervical cancer.[87] The transfer of the specimen from the gynecologist-surgeon[88] to the researcher stemmed from a personal and professional relationship between them and never involved the patient whose cells would produce a profoundly valuable cell line.[89] In fact the standard practice was, and remains, that anything removed from the body during medical treatment- classified as medical waste or discarded pathology specimens-[90] can be used for research purposes so long as the facility obtaining the material has the permission of an Institutional Review Board.[91] These permissions are generally granted under an exempt status, meaning that no consent is required for the use of otherwise discarded materials.[92] The rationale behind an exempt status is that the uses of the material are diverse and not easily articulated in a consent form.[93] Furthermore, the researcher may not know the specific use of a specific specimen when that specimen is received, making it very difficult to

[86] 45 C.F.R. 46 §101(b) (2005).

[87] SKLOOT, *supra* note 85.

[88] *Id.* Ironically, the gynecologist-surgeon who operated on Henrietta Lacks was Dr. Howard Jones, who would go on to found the Jones Institute, which pioneered the IVF process in the United States.

[89] *Id.* Furthermore, as a demonstration of the prominence of the HeLa cell line, a Google search of "HeLa cell line" produced over one million hits.

[90] *Id*.

[91] OTA REPORT, *supra* note 65, at 95.

[92] *See* 45 C.F.R. 46 §101 (b) (2005).

[93] *Id*.

engage a patient in an informed consent process.[94] Finally, there is a pervasive sentiment in both courts and legislatures that the specimens in question are removed to benefit the patient and thus should be usable by the researchers because they are not usable and are in fact harmful to the patient but have real potential to contribute to the advancement of science.[95]

In light of the history of lack of consent and free use for research purposes of discarded biological specimens, the court in *Moore* sought to balance these competing personal and public policy interests.[96] The court held that there could be no tort of conversion for one's own genetic material because the right was not akin to a property right.[97] They relied largely on the lack of holdings indicating a property right in one's own genetic material as well as the profound public policy concerns of substantially limiting researcher's access to specimens if patients retained an ownership right in their genetic material, even after researchers had altered it significantly by investing considerable time and resources.[98]

The court largely fails to consider possible structures for recognizing some form of a quasi-property right in genetic material. Scholars have considered possible modes of allowing for compensation for uniquely useful cell and tissue specimens, which are admittedly a very small portion of all collected specimens, which includes rights similar to the right of publicity as well as contract-based system that would seek to keep the transaction costs feared by many in

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[94] OTA REPORT, *supra* note 65, at 106-108; 45 C.F.R. §46.101(b) (2005)(exempting certain research from IRB monitoring and reporting once an exemption has been granted).

[95] *Moore*, 51 Cal. 3d at 131; OTA REPORT, *supra* note 65, at 71.

[96] *Id.* at 140.

[97] *Id.* at 135.

[98] *Id*. at 135-42 (also providing a preference for the legislature to be the forum for any extension of the tort of conversion to genetic material).

check.[99] These proposals attempt to balance the fact that substantial time and resources must be expended to develop a cell line and derive profits with the reality that without the cell or tissue donor there would be no cell line.[100] Public policy based arguments that compensation should only be available for replenishable cells and tissues rely on a slippery slope argument that ends with the purchase of human organs by the rich and the exploitation of the poor.[101] However, these arguments fail to consider that unique genetic sequences are rare and their occurrence is largely by chance. It is not something that can be exploited in the sense that anyone has the ability to offer their DNA to the highest bidder. Biotech companies take substantial risks in attempting to develop a profitable product and their success is in part chance and luck. Furthermore, the "replenishable cells" argument- applied to blood and semen- is somewhat inaccurate because the United States also allows payment for human oocytes, which are not replenishable, albeit available in numbers greater than any individual would need or use. However, this is not unlike kidneys, with which a human can function fine with one, or a liver, which can regenerate itself over time and the sale of either would be illegal.

Further complicating the argument is the reality that an attempt at growing a cell line will result in countless failures, each time teaching something, en route to the success. Must all of the individuals who contributed to failed cell lines that taught a critical lesson also be compensated? Evaluation of the "normal" is critically important to understanding the "abnormal," making patients who contribute to the comparative "normative" pool of data just as important as those

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[99] Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 258-59 (1986).

[100] *Id*. at 228.

[101] Thomas P. Dillon, *Source Compensation for Tissues and Cells used in Biotechnical Research: Why A Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628 (1989).

that have "abnormal" characteristics and creating a situation where all patients that contribute to research data could legitimately seek compensation for their apportioned contribution to an advancement in science.

The *Moore* court held that the requirement of informed consent to the research use of the specimens sufficiently balanced the patient's interests with those of the researcher.[102] The court largely relies on *Cobbs v. Grant*[103] for a review of the informed consent process. The court reiterates that without informed consent, the physician is liable for breach of duty and negligence.[104] Additionally, informed consent requires that the patient be advised about all reasonable options for care and given the right to refuse treatment.[105] Without these components, the consent is not informed.[106] The *Moore* court felt that so long as this standard of informed consent was upheld, that the interests of the patient and the researcher would be adequately balanced.[107] The court found that the defendants had breached this duty[108] and a lack of future litigation related to Moore's claim for lack of informed consent suggests that this claim was settled out of court.

Moore's case highlights the complex ways in which treatment and research intersect. While finding that an individual does not retain a property right in their own genetic material,

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[102] *Moore*, 51 Cal.3d at 144.

[103] Cobbs v. Grant, 502 P.2d 1, _ (Cal. 1972)

[104] *Id.*

[105] *Id*.

[106] *Moore*, 51 Cal.3d at 144.

[107] *Id.*

[108] *Id*.

and that individual does not stand to profit from the use of their material, the case did not address the larger question of whether or not DNA sequences should be patentable at all. Scholarship written while Moore's case was being appealed did address the possibility that the courts would consider the overall patentability of genetic sequences, largely stemming from the concordant work on the human genome and the rapid rate of discovery of unique genes that had the potential to be exceptionally profitable.[109] Arguments for allowing the patenting of gene sequences without compensation to the patient largely rely on the investment of resources, both time and money, by the pharmaceutical industry to develop profitable products, the fact that gene sequences are not specifically useful unless isolated, the limited amount of funding provided by the government to the project,[110] and the harm that patients would cause to the free flow of information between researchers which maximizes the benefits of the work on the human genome.[111] None of these arguments truly grapple with the issue of whether or not cell lines should be developed from IRB exempt protocols that do not require consent. This is not to say that consent must be required or that patients would be unwilling to sign consents about the use of discarded specimens. We must make a determination, as a society, about how important the advancement of science is to us and how to weigh the benefits it provides to medicine as a whole, which arguably transfers its benefits back to all members of society. Perhaps it is reasonable to require patients undergoing medical care to make this small contribution towards future developments in medical care by allowing their discarded specimens to be used in

[109] *See* Rebecca S. Eisenberg, *Genetics and the Law: Patenting the Human Genome*, 39 EMORY L.J. 721, 722-24 (1990).

[110] *See id.* at 739.

[111] *See* Dillon, *supra* note 101, at 633.

research for any purpose, but perhaps this should be made clear to individuals. The OTA Report does consider this issue, but only argues both sides and fails to truly take a position.[112]

For a moment in August 2010, it seemed that genes may no longer be patentable when the US PTO challenged the patents held on the BRCA1/2[113] gene sequences.[114] The Southern District of New York initially held that neither the composition of a gene sequence, the method for isolating individual gene sequences, nor the process of evaluating the presence or absence of the BRCA genes was patentable.[115] Genetic testing, specifically the screening for a certain gene mutation or collection of mutations is generally accomplished by obtaining a figurative chromosomal map of the location of the relative markers called a probe. Samples can them be compared to the probe to evaluate the presence or absence of the markers in question. For single gene defects, like cystic fibrosis which is caused by many potential different mutations, comparison to a probe will allow for determination of carrier, non-carrier or affected status of a sample. For more complex polygenetic diseases, like breast and ovarian cancer, the presence or absence of mutations can lead to the composition of a risk profile for the individual in question, with varied risks of manifestation of the disease based on how many mutations are present and where they are located. Essentially, the monopoly granted to Myriad made them the sole

[112] OTA REPORT, *supra* note 65, at 93-115.

[113] The BRCA1/2 gene sequences mark the specific chromosomal locations and genetic mutations that increase likelihood of breast and/or ovarian cancer substantially. The company holding the patents markets the test for the BRCA1/2 gene screening test exclusively.

[114] Assn. for Molecular Pathology v. U.S. Pat. and Trademark Off., 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[115] *Id.*

provider of BRCA screening because they held the patents associated the comparing an individual's genetics to a mapped BRCA profile.[116]

The case was appealed, vacated by the Supreme Court, and reheard in the United State Court of Appeals, Federal Circuit in 2012.[117] In this most current analysis, the court adamantly refused to consider the public policy benefits or harms resulting from permitting a single company to control access to BRCA screening and stated that all they were addressing was "patent eligibility, not patentability."[118] With respect to the composition claims, the court found that the isolated BRCA genes were patentable because the form in which they existed for use by Myriad was not identical to the form in which they exist in the human body.[119] Furthermore, this difference in form, which results from the biochemical extraction of non-coding genes between the relevant BRCA genes, is a "product of human ingenuity."[120] Of particular interest, the court states that although, in general, the purification of natural products does not create a new product that is patentable, DNA is unique in that the process of isolating specific genes (which the court likens to a purification) is patentable.[121] The determination of uniqueness for the purpose of patentability hinges on how the isolated DNA is different from the original, natural form as

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[116] *Assn. for Molecular Pathology*, 702 F. Supp. 2d at 181.

[117] Assn. for Molecular Pathology v. U.S. Pat. and Trademark Off., 689 F.3d 1303 (Fed. Cir. 2012).

[118] *Id.* at 1324.

[119] *Id.*

[120] *Id.*

[121] *Assn. for Molecular Pathology*, 689 F.3d at 1339.

opposed to how it is the same.[122] For these reasons, the screening process of evaluating a sample of the presence of BRCA genes is also patentable.[123] The court upheld the SDNY's determination that the patents for the method of comparing a sample to the BRCA gene maps were invalid because these were abstract mental processes.[124]

This holding largely leaves the patents owned by Myriad, and their ability to profit exclusively off of their technology intact. The court repeatedly expressed an unwillingness to make a sweeping change to patent law when Congress has failed to act.[125] This reluctance could be further supported by the inherent limitation on patent duration. In this case, Myriad's patents will begin to expire in December of 2015 anyway. Since the Court of Appeals for the Federal Circuit has officially declared their intention not to speak on the reasonableness of permitting patents on gene sequences, any substantial change in the immediate future would have to come from Congress.

Even if gene sequences were no longer patent eligible, whether the creation of cell lines would be considered sufficiently "markedly different" from the original DNA sequence to warrant patent protection remains to be decided. This issue has yet to be specifically litigated because the cases have consistently turned on other facts.[126] However, the tension in the scholarship over whether or not to grant any quasi-property rights is primarily rooted in the

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[122] *Assn. for Molecular Pathology*, 689 F.3d at 1340.

[123] *Id.*

[124] *Id.*

[125] *Id.* at 1341.

[126] *Moore*, 51 Cal. 3d at 144 (deciding the case by weighing interests of science against the interest of the individual in obtaining "property right" in tissue).

useful and patentable contribution of the tissue or cell donor to the overall process of making a patentable and profitable product.[127] If the genetic contribution is deemed per se unpatentable, then it follows logically that the donor's contribution is of no commercial value. All commercial value would be in the genetic alterations that the researchers would need to perform in order to have a patentable product. As a result, the status quo of not paying donor's for their genetic material could be preserved.

This would also alleviate a substantial concern for DNA banks that hold potentially valuable genetic information. Furthermore, this would cause less upset to the use of research exempt protocols for the collection of specimens. If the contribution is per se altruistic, then the need for informed consent as a balancing of interests between patient and researcher becomes less compelling. Researchers would continue to have access to a steady flow of specimens for research purposes without fear of costly litigation and in return, could only seek patents for products that are "markedly different" from those that occur in nature.

IV. Privacy Concerns In Creating DNA Banks

DNA, by its very nature, cannot be "deidentified" in the way that traditional data can be and is required to be by Institutional Review Boards (IRBs), which review and approve human research.[128] DNA is inherently unique to each individual and a DNA profile can be linked back

[127] *See* Rebecca S. Eisenberg, *Genetics and the Law: Patenting the Human Genome*, 39 EMORY L.J. 721 (1990); Thomas P. Dillon, *Source Compensation for Tissues and Cells used in Biotechnical Research: Why A Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628 (1980); Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 258-59 (1986).

[128] *See* Health Insurance Portability and Accountability Act, Pub. L No. 104-91, 110 Stat. 1936 (1996); 45 C.F.R. § 46 (2005).

to its origin as well as linked to individuals closely related to the origin.[129] Access to DNA profiles could theoretically grant access to the identification of any individual found to be a DNA match to a banked profile. While it may seem unlikely that information from a DNA bank would be in the public domain, many major medical journals that publish the research studies on DNA profiles require otherwise.[130]

Many major medical journals require that researchers seeking to publish a paper referring to SNP profiles publish access the "deidentified" profiles in conjunction.[131] This requirement is meant to allow for the mathematical validation of the research to be subject to critical scrutiny and repetition/validation by the scientific community at large while recognizing that most members of this community do not have the resources or facilities to produce their own SNP profiles for validation. While this does not solve the problem of validating the technique of creating SNP profiles itself[132] this does allow for mathematical validation of claimed significant results. It is unclear if these journals are unconcerned about potential "reidentification" of individuals based on their published "deidentified" SNP profiles or if they have simply not

[129] Each individual obtains 50% of their DNA from each parent. As a result, siblings share approximately 25% of their DNA. Father and son matching is even easier because the Y-chromosome, which distinguishes maleness, is always inherited from the father so patralineal lines share the same Y chromosome.

[130] These journals are typically the most prestigious and require that SNP data be both comply with the Minimum Information About Microarray Experiment (MIAME) standards (http://www.mged.org/Workgroups/MIAME/miame.html) and be published with one of three public repositories Gene Expression Omnibus (GEO) (http://www.ncbi.nlm.nih.gov/geo/), ArrayExpress (http://www.ebi.ac.uk/arrayexpress) or Center for Information Biology gene Expression database (CIBEX) (http://cibex.nig.ac.jp).

[131] MIAME STANDARDS, http://www.mged.org/Workgroups/MIAME/miame.html (last visited Mar. 19, 2011).

[132] The repetitive DNA fingerprinting that occurs as part of the research protocol provides this validation.

contemplated the possibility. This issue does not exist for qPCR analysis because with this technique, the only portions of the chromosomes being evaluated are those that are the same in all humans rather than the portions that are different. Publication of qPCR results does not provide the potential means for reidentification as SNP profiles do.

The Health Insurance Portability and Accountability Act (HIPAA) was the first real attempt at federal regulation that sought to control and regulate the sharing of health information traditionally contained in a patient medical record.[133] HIPAA effectively created the concept of "protected health information."[134] HIPAA distinguishes between information that is "non-identifying," such as an individual's age, and information that is "identifying," such as an individual's date of birth, and requires non-identifying and identifying personal and health information to be treated differently.[135] Although most people believe that the purpose of HIPAA is to improve patient privacy protections, the actual purpose was contemplation of what regulations and procedures would need to be in place to keep patient information secure as electronic medical records (EMR) became increasingly prevalent.[136] Given that HIPAA was not actually about patient privacy, it is reasonable to assume that genetic privacy was not fully contemplated in 1996 when the act was passed. Furthermore, genetic information is not

[133] Health Insurance Portability and Accountability Act, Pub. L No. 104-91, 110 Stat. 1936 (1996).

[134] *Id*.

[135] *Id*.

[136] *Id*.

specifically listed as a category of protected health information, although some pieces of genetic information might fall under the broader category of past, present or future health condition.[137]

However, the Genetic Information Nondisclosure Act of 2008 (GINA) was clearly contemplating the privacy concerns stemming from our increased knowledge about the human genome.[138] The focus of GINA is to help ensure that genetic information is not obtained without authorization from the individual who provided it and to protect against discrimination stemming from knowledge of genetic information.[139] GINA focuses in on three key areas of potential abuse of genetic information: private insurance companies (self-insured plans as well as traditional plans are addressed), Medicare insurance plans, and employment discrimination (including employment agencies, unions and training programs).[140] GINA specifically seeks to define confidentiality with regards to genetic information.[141] §206(a) defines genetic information collected by an employer as confidential medical information, although it is unclear to what degree this description overlaps with the "protected health information" contemplated by HIPAA. GINA appears to allow for the release of genetic information in a limited number of circumstances including: request by the employee in writing, research, in response to a court order, to government officials ensuring compliance with GINA, as needed to comply with the

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[137] Health Insurance Portability and Accountability Act, Pub. L No. 104-91, 110 Stat. 1936 (1996). Genetic information that indicates the present of a current or future known illness would clearly fall into this category (e.g. cystic fibrosis or Huntington's disease). However, a genetic disposition to a certain eye color or height would not seem to fall into this category.

[138] Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, 112 Stat. 881 (2008).

[139] *Id*.

[140] *Id*.

[141] *Id*. at §206.

Family Medical Leave Act and as required by reporting requirements to the Center for Disease Control.[142] Perhaps the most glaringly broad category is §206(b)(2), research. The act does not attempt to advise on what kinds of "research" might fall within this broad category or under what circumstances it might be permissible or impermissible to release genetic information.[143] Furthermore, it may very well be unclear who "owns" the right to release the genetic information at all.[144]

GINA makes no attempt to tackle the complex questions of ownership of genetic materials in the context of who would be protected by the confidentiality provisions of the law. It is unclear if an individual is found to not have legal ownership of a stem cell line derived from their tissue has any type of claim to confidentiality under GINA. Given that GINA was drafted while work on the human genome was nearing completion[145] there was reason to hope that the law would seek to better address the issues specific to genetic information in a way that HIPAA did not. If anything, the language in GINA may potentially make issues surrounding privacy of genetic information more complicated.

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[142] Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, §206, 112 Stat. 881 (2008).

[143] *See* OFFICE OF HUMAN RESEARCH PROTECTION, *Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards*, http://www.hhs.gov/ohrp/policy/gina.html (last visited Mar. 27, 2011).

[144] *See supra* Section III (discussing issues of ownership of genetic material).

[145] HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml (last visited Sept. 25, 2011).

GINA makes an exception for "inadvertent discovery" of genetic information, but largely fails to define this concept.[146] It is largely unclear what would or would not qualify as an "inadvertent discovery" of an individual's genetic information or how that determination would be made. Although the issue has not yet been litigated,[147] it seems as though it would largely be a case-by-case, fact based determination of "inadvertent" with the burden falling on the party that has obtained the information to show that they did not actively seek out the information against the will of the individual claiming confidentiality.[148] However, since there is a "research" exception to the confidentiality requirement, it is unclear whether or not confidentiality would extend if the use was a bona fide research use, including compliance with all de-identification requirements, but the sample was later re-identified in a another context. It is critical to reiterate the fact that DNA cannot be de-identified in the same way that a traditional medical record can be. The possibility of re-identification always exists and should be considered in contemplating how to craft the notion of confidentiality and privacy protections as they relate to genetic materials. Perhaps the best guideline would be to follow a plain meaning to "inadvertent" and consider whether the intent of the party holding the contentious information was to gain possession of the information or not.[149] This would require an analysis of facts as

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[146] Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, §102(d)(3), 112 Stat. 881 (2008).

[147] To date, there are no cases seeking to litigate the meaning of "incidental discovery" within GINA.

[148] *See* Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, §§ 102(d)(3); 102(d)(1), 112 Stat. 881 (2008).

[149] *See generally* Patricia A. Roche & George J. Annas, *DNA Testing, Banking, and Genetic Privacy*, 355 N. ENGL. MED. J. 6, 545-46 (2006) (discussing the privacy concerns that arise from banking DNA data and the limits of current laws to offer protection).

well as potential motive and the evaluation may effectively be moot anyway because seeking to retract genetic information is like trying to unring a bell. While a court could require an insurance company to offer rates as though the information does not exist or require an employer to treat an employee, there is no way to effectively control the fact that the knowledge exists.

Another potential confounding issue in GINA is that the language of the statute prohibits "requesting, requiring or purchasing" otherwise confidential information.[150] This language would likely overlap with the notion of inadvertent discovery in a dispute over how confidential information was obtained. However, there could certainly be cases where information is intentionally sought and discovered without "requesting, requiring or purchasing" that information. For example, if SNP profiles were obtained from a medical journal publisher and re-identified, it is unclear if this would create a GINA violation. While the acquisition of the information does not seem "inadvertent" it is not clearly "requesting, requiring or purchasing the information." There is an argument to be made that it is "purchasing" since the technology to re-identify an individual will certainly have a cost. Perhaps more problematic is that in this scenario, it is unclear how an individual would even know that an insurance company or employer possessed information about them that would otherwise be presumed confidential.

In considering how to provide individuals access to their SNP profile information in conjunction with addressing privacy concerns stemming from the publication and banking of that information, we must consider whether GINA will be adequate or if another structure will need to be developed and put into place. Furthermore, neither HIPAA nor GINA thoroughly considered the role of research protocols in the collection of SNPs or the complex evaluation of

[150] Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, § 102(d)(1), 112 Stat. 881 (2008).

ownership of genetic information in seeking to accomplish public policy goals of protecting the privacy of health and genetic information. Research protocols are generally subject to their own governing bodies and generally operate under the assumption of the ability to separate a patient from their data.[151] Ownership of genetic information, though clearly a thorny issue, is a critical determination in an evaluation of privacy because if the individual contributing the DNA is not considered the owner of the information, it is unclear what their claim to privacy would be. Public policy considerations of furthering science have been cited as driving decisions about ownership of genetic material[152] as well as current research standard practice.[153] It is inevitable that the interests of all the parties involved will clash and legislatures and courts will need to weigh those interests and make determinations of how to adequately balance them.

V. Physician Liability in the Creation Of SNP Profiles and DNA Banks

The notion of a duty to a third party, not in privity with the tortfeasor, has a limited application. The foundation for the concept was laid in *Palsgraf*, where Justice Cardozo suggested that the element of foreseeability was an essential component of the duty analysis in tort law.[154] The concept was significantly expanded in *Tarasoff v. Reagents of the University of California*[155] where the court found a duty existed when harm was foreseeable.[156] In order for

[151] *See supra* Section II.

[152] *Supra* notes 92-94 and accompanying text.

[153] *Supra* notes 105-108 and accompanying text.

[154] Palsgraf v. Long Island R. Co., 162 N.E. 99 (N.Y. 1928).

[155] Tarasoff v. Regents of U. of California, 551 P. 2d 334 (Cal. 1976).

the circumstances to give rise to the duty to warn a third party, four factors must be considered.[157] The first is that the patient must be engaging in dangerous behaviors.[158] The second is that the harm must be foreseeable.[159] The third is that there must be a special relationship between the person with the duty and the person posing the threat.[160] And finally, the risk of the harm must be identifiable.[161] These factors, perhaps standing for a high water mark of duty to a third party, have been cited by courts considering the imposition of a duty on a physician to a third party potentially affected by a genetic illness.[162]

Physician duties related to genetic diagnosis were specifically considered in *Andalon v. Plowman*.[163] In this case, parents of a child born with Down's Syndrome claimed medical malpractice for failure to counsel on risks of Down's Syndrome in pregnancy and offer prenatal testing.[164] The parents brought the case both on their own behalf was well as on behalf of their

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[156] *Tarasoff*, 551 P.2d at 334. Specifically, a psychotherapist was held to have a duty to warn an individual against who a patient had made credible threats of harm.

[157] *Id.*

[158] *Id*.

[159] *Id*.

[160] *Tarasoff*, 551 P.2d at 334.

[161] *Id*.

[162] Safer v. Estate of Pack, 677 A.2d 1188 (N.J. Super. App. Div. 1996); *see also* Jeffrey W. Burnett, Comment, *A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease*, 36 HOUS. L. REV. 559 (1999) (discussing the application of the *Tarasoff* factors to the duty to disclose genetic illnesses to a third party).

[163] Andalon v. Super. Ct., 162 Cal. App. 3d 600 (Ct. App. 1984).

[164] *Id.* at 604.

child.[165] The court explicitly considered a physician's duty to a third party as it related to foreseeability.[166] The court acknowledged that importing foreseeability into the duty analysis had the possibility of either expanding or limiting physician liability.[167] A physician's liability would be limited if the harm was caused by his negligence, but not foreseeable.[168] However, liability would be expanded if the harm was foreseeable, but not caused by the physician.[169] The court accepted this peculiar calculus and held the physician liable.[170] Allowing a profound expansion of liability whenever harm is foreseeable creates a situation in medical genetics cases where liability seems practically inescapable because genetics are inherently predictable, though perhaps the predicted risk is very small, and therefore foreseeable.

In considering a very specific breed of tort- medical genetics- courts have relied on various compilations of more common tort language[171] to balance a desire to limit physician duty

[165] *Andalon*, 162 Cal. App. 3d at 604.

[166] *Id.* at 610.

[167] *Id.*

[168] *Id.*

[169] *Andalon*, 162 Cal. App. 3d at 610.

[170] *Id*. at 611.

[171] Courts use claims of "wrongful birth", "wrongful life," "wrongful conception" and "wrongful pregnancy" to stand for different causes of action. However, these terms may be used interchangeably resulting in inconsistency in opinions. Very few jurisdictions acknowledge a claim brought by a child that they never should have been born (most commonly called wrongful life) while most acknowledge an action brought by parents that but for the physician's negligence related to diagnosing a genetic illness they would not have pursued the pregnancy (most commonly called wrongful birth). *See, e.g.*, Schroeder v. Perkel, 432 A.2d 834 (N.J. 1981); Pate v. Threlkel, 661 So. 2d 278 (Fla. 1995); Doolan v. IVF America*, Inc.*, 12 Mass. L. Rep. 482 (Mass. Super. 2000); McCallister v. Ha, 126 N.C. App 326 (N.C. Ct. App. 1997). Most also acknowledge an action that but for the physician's negligent sterilization they would not have obtained a pregnancy (usually labeled wrongful conception/pregnancy), though a claim for

to a third party with the reality that a genetic illness intrinsically suggests foreseeability of harm. In the 1970s, with the rapid development of technology to diagnose genetic illness carrier status[172] in adults of childbearing age as well as the availability of amniocentesis for the diagnosis of genetic illness in an unborn child, the possibility of medical genetics torts came into existence. In 1983, a Washington court considered certified questions of whether a parent has a right to have a child free from "defects" and if the physician has a duty to provide the best possible care to guarantee that right.[173] The court answered both of these certified questions in the affirmative.[174] Furthermore, the court held that a physician could have a duty to pre-conception counseling if the risk of harm to a potential child was foreseeable and that if this duty was found to exist, proximate cause would follow as a matter of a law in a tort suit.[175] While the harm caused to the children in this case stemmed from the teratogenic effects of an anti-seizure medication prescribed during pregnancy,[176] the concept of liability following foreseeability proved portable to medical genetics cases.

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recovery for a healthy child born from a failed sterilization often fails. *See also supra* notes 75-79.

[172] The ability to diagnosis the disease is far less significant to this analysis than the ability to diagnosis carrier status. An individual who knows that they are affected with a genetic disorder are very likely to seek counseling on the risks of passing the disorder on to children. Individuals who are carriers (meaning they carry one copy of a mutated gene and two copies are required for the disease to be manifest) are generally unaware of their carrier status though able to produce an affected child if the other parent is also a carrier.

[173] Harbeson v. Parke-Davis, Inc., 656 P.2d 483, 488 (Wash. 1983).

[174] *Id*. at 493.

[175] *Id*. at 493.

[176] *Id*. at 494.

In 1981, New Jersey was the first court to take up the issue of physician liability for failure to diagnosis a genetic condition and the resultant birth a second, affected child.[177] In this case, parents and children[178] brought suit after the first child was not diagnosed with cystic fibrosis[179] until the mother was in her eighth month of pregnancy with her second child, who was also affected with the disease. The defendants argued that their duty to diagnose the disease was only to the first child and did not extend to her parents, precluding any liability related to the birth of the second child.[180] The court vehemently rejected this argument, holding that a physician's duty extends beyond the patient if other family members would be adversely affected by a breach and that harm was foreseeable.[181] Furthermore, the court states that public policy should place the additional costs associated with raising a sick child on the negligent party.[182] While the court stops short of recognizing a true "wrongful birth" action in the sense of stating it would be better if the child had never been born, it did comment that "[t]here is no joy in watching a child suffer and die."[183]

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[177] Schroeder v. Perkel, 432 A.2d 834 (N.J. 1981).

[178] The children brought "wrongful life" claims which are not evaluated in this opinion and are permitted in only a limited number of jurisdictions.

[179] Cystic fibrosis affects the production of fluids within the body and is primarily a disease impacting the pulmonary and digestive tracks. The disease is fatal and inherited in a recessive pattern.

[180] *Schroeder*, 432 A.2d at 838.

[181] *Id.* at 839.

[182] *Id.* at 842.

[183] *Id.*

In 1995, a Florida court considered a similar question of how far to extend physician liability for failure to diagnose a genetic condition.[184] In this case, the court held that the physician's failure to diagnose an inheritable cancer harmed a child of his patient who developed the same cancer and contended that her treatment would have been different if she had known about her increased risk of illness at an earlier date.[185] The court's analysis focused on the duty as defined by statute[186] and the children as third party beneficiaries, and as such, there was no need for privity between them and their parent's doctor.[187] However, the court specifically held that the duty to disclose the presence of a genetic illness extends exclusively to the patient, with the assumption that the patient will pass the information on to their children.[188]

In contrast, a New Jersey court held that the physician's duty to warn does actually extend to the children of the patient.[189] In facts almost identical to those in *Pate*[190] the court extended the actual duty to third parties citing the avoidance of harm from genetic conditions as comparable to the avoidance of harm from contagious diseases or the threat of physical harm.[191] However, the court does recognize the potential for a case where the duty to disclose to a third

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[184] Pate v. Threlkel, 661 So. 2d 278 (Fla. 1995).

[185] *Id.* at 279.

[186] *Id.* at 280.

[187] *Id.* at 281.

[188] *Pate*, 661 So. 2d at 282.

[189] *Safer*, 677 A.2d at 1192-93 (stating an explicit refusal to hold that the duty to warn is satisfied by warning the patient as held in *Pate*).

[190] *See supra* notes 176-80.

[191] *Safer*, 677 A.2d at 1192-93.

party could conflict with the duties of confidentiality and privacy that the physician has to a patient.[192] To date, this conflict of duties has not been litigated.

While claims brought by an affected child remain difficult to sustain at best,[193] parents generally have good success in obtaining the increased costs of raising a child with a genetic illness though limited success at claiming emotional harm or wrongful birth.[194] The success of the claim generally hinges on whether the parents' genetic illness carrier status should have been foreseeable to the treating physician.[195] Another caveat is that the illness causing the claimed "injury" must be definitively genetic in nature.[196] Furthermore, any claim of a physician's third party duty must show actual, foreseeable injury.[197]

In considering how this body of law creating a duty to a third party applies to SNP profiles, it is important to keep in mind the ways in which SNP profiles differ from the genetic

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[192] *Safer*, 677 A.2d at 1192.

[193] *See* Doolan v. IVF Am. (MA), Inc., No. 993476, 2000 WL 33170944 (Mass. Super. Nov. 20, 2000); Bergero v. Univ. of S. California Keck Sch. of Med., No. B200595, 2009 WL 946874 (Cal. Ct. App. Apr. 9, 2009).

[194] *See* Doolan v. IVF Am. (MA), Inc., 993476, 2000 WL 33170944 (Mass. Super. Nov. 20, 2000); *Schroeder*, 432 A.2d at 838; McAllister v. Ha, 485 S.E.2d 84 (N.C. App. 1997) (note: claim is labeled wrongful conception in this case but looks more like what other courts have called wrongful birth).

[195] Munro v. Regents of Univ. of California, 263 Cal. Rptr. 878 (Cal. Ct. App. 1989) (finding no duty to offer patients testing for Tay Sachs when neither reported being of Ashkenazi Jewish or Prince Edward Island descent during genetic counseling session).

[196] Williams v. Univ. of Chicago Hospitals, 667 N.E.2d 738 (Ill. App. 3d 1996) (holding no duty to a third party when a child with ADHD is born following a failed bilateral tubal ligation sterilization procedure and physician is not responsible for any additional costs associated with raising a child with ADHD).

[197] Dehn v. Edgecombe, 865 A.2d 603 (Md. 2005) (finding no physician duty to a wife who became pregnant and delivered a healthy following her husband's vasectomy because a healthy child is not an "injury" within the meaning of tort law).

illness occurring in the cases. First, SNPs do not detect single gene defects.[198] SNPs detect only whether or not there are two copies of each chromosome (copy number analysis), genotype analysis, and they may be able to detect certain translocations.[199] In evaluating a SNP profile's usefulness in predicting illness, SNPs can only project risk ratios and cannot take into consideration ranges of disease presentation and environmental factors that may alter the manifestation of a disease. This is dramatically different from a disease such as sickle cell anemia. Sickle cell anemia results from the alteration of a single nucleic acid and causes an illness with lifelong complications and often a shortened lifespan. Each carrier parent carries one copy of the altered nucleic acid. Together, they have a 25% chance of producing a non-carrier child, a 50% chance of producing a carrier child and a 25% chance of producing an affected child. The risk of having an affected child can be predicted with very high accuracy dependent on the child's parent's carrier status. SNPs are statistical models providing likelihood of disease occurrence.[200] Given their complex and indefinite nature, it is very unclear how a

[198] Cystic fibrosis, Tay-Sachs, Sickle Cell, and Fabry's disease are all examples of single gene defects.

[199] Translocations occur when the arms of a chromosome exchange genetic material with each other. They can be balanced (when the amount of information exchanged is even) and this condition may compatible with life. Many people will remain unaware that they carry a translocation until they attempt to reproduce. Certain translocations occur with such frequency as to warrant naming as a disorder. For example, Robertsonian translocations are whole-arm translocations of chromosomes 13, 14, 15, 21, or 22. Translocations can also be unbalanced (when the exchange of information is uneven) and this is generally incompatible with life. Depending on the size and location of the translocation it may be detectable by a SNP profile.

[200] Similar to the breast cancer genes (BRCAI and II), the presence of which indicates a substantially increased risk of breast and/or ovarian cancer, but no assurance that the disease will ever manifest itself.

court would interpret a physician's duty to counsel in relation to a SNP profile.[201] Liability stemming from a failure to diagnose cystic fibrosis has been litigated and also provides some information about a court's willingness to impose liability based on risk ratios. Cystic fibrosis has a complex inheritance pattern with both public and private mutations documented, though cystic fibrosis screening is traditionally limited to public mutations only. When both parents have been found to carry a public mutation, their risk of having a live-born child affected with cystic fibrosis is approximately 1 in 6, or 16.67%, though this number provides no indication of the severity of the presentation of the illness or the child's life span. Courts have demonstrated a clear willingness to enforce a duty in the presence of a 16.67% chance of the occurrence of illness.[202]

In contrast, the court in *Munro* refused to impose a duty when the foreseeable likelihood of Tay Sachs was effectively that of the general population.[203] Approximately 1 in 300 individuals in the general population is a carrier of a Tay-Sachs mutation while approximately 1 in 30 individuals of Ashkenazi Jewish decent are carriers.[204] Individuals of French Canadian decent and Cajun decent are also at a heightened risk to carry the mutation.[205] As a result, the American College of Obstetricians and Gynecologists (ACOG) released guidelines in 1991

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[201] *See Williams*, 667 N.E.2d at 738 (Ill. App. 3d 1996) (refusing to hold physician liable for ADHD child born after a sterilization operation).

[202] *See* Schroeder v. Perkel, 432 A.2d 834 (N.J. 1981).

[203] *Munro*, 263 Cal. Rptr. at 878 (holding no duty when neither of the patients had indicated having ancestry from a high-risk group, although it was later discovered that one patient was of French-Canadian decent).

[204] ACOG COMMITTEE OPINION, NO. 318. SCREENING FOR TAY-SACHS DISEASE (2005).

[205] *Id*.

indicating that when either party belongs to a high-risk group, then that party should be screened for Tay-Sachs mutations and if one member of the couple is a carrier, then the other member should also be screened to appropriately counsel them on the likelihood of having an affected child.[206] While there has not yet been a case reported where there was a failure to test patients who were in a reportedly high-risk group for Tay-Sachs, it seems likely, given the sympathetic nature of the would-be plaintiffs and the horrific nature of the disease coupled with the ACOG guidelines, that the court would find a duty to counsel. Without genetic counseling, the risk of an affected child in a high-risk population is approximately 1 in 3,600 (1/30 from each parent creating a 1/900 risk and then 1/4 chance of the child being affected, creating an overall risk of an affected child to be 1/3,600), while in the general population it is 1 in 360,000 (1/300 from each parent creating a 1/90,000 risk then 1/4 chance of the child being affected, creating an overall risk of an affected child to be 1/360,000). If a court did enforce liability, that court would be doing so given an incidence of 0.0003% likelihood of illness between two individuals belonging to a high risk group, suggesting a reliance on a duty stemming from professional guidelines[207] that advise testing rather than on the actual likelihood of disease occurrence.

In returning to consideration of litigation regarding SNP profiles, it remains unclear when a court would consider the duty to come into being. While a 1 in 6 risk clearly invokes the duty, it remains to be seen whether a duty only exists if the risk is greater than 16.67% or if lesser risks are also invocative of a duty to counsel. For example, if the incidence of disease X is 1 in

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[206] ACOG COMMITTEE OPINION, NO. 318. SCREENING FOR TAY-SACHS DISEASE (2005).

[207] The importance of these guidelines cannot be overstated. The cost of testing for Tay Sachs is thousands of dollars for each patient. Without ACOG guidelines recommending testing in specific groups, insurance companies are unlikely to cover the costs of the tests, making then unavailable to most patients.

100,000 in the general population, how much of an increased risk would be required to create a physician duty to the patient or to a third party? 1 in 50,000? 1 in 500? Furthermore, it is unknown whether courts would be willing to litigate risk ratios alone or whether some kind guidelines would be needed to advise on what the risk thresholds were that rise to the level of obligatory counseling and the creation of a duty.[208] Before courts can effectively establish standards of care and impose duties with respect to SNP profiles, these guidelines need to be established and enforceable.

Courts will also need to consider on which physician liability falls in the interpretation of SNP profiles. SNPs are created and interpreted by molecular biologists who have limited understanding of their clinical implications.[209] Additionally, SNP profiles composed of several hundred thousand SNPs are primarily created in infertility medicine as a technique for research validation. Not only are the SNP profile results not intended to provide disease risk assessment profiles to patients, but reproductive endocrinologists are ill-equipped to advise patients on their potential for heart disease or Alzheimer's given their SNP profile. However, it is unclear if most regular cardiologists or geriatricians would be any better suited given the highly complex nature of SNP profiles. At this time, there remains a substantial gap between the research-driven use of SNPs and their potential clinical applications, indicating a need for centralization and organization of the information in a way that is usable and effective. There is currently no way to predict a potential liability stemming from holding a SNP profile due to the complexity of the risk-ratio. There is also no cost-effective way to impose counseling responsibilities on the

[208] *See infra* Part VI, for a discussion of the development of guidelines with respect to SNP risk profiles.

[209] An SNP report is graphical in nature. A person who understands both the clinical (MD) and molecular (PhD) aspects of the results must interpret them for patients and for the purposes of publication.

molecular biologists and physicians that create SNP profiles for research purposes and are not equipped to counsel patients on the meaning of all the information currently known to exist in SNP profiles or the meaning that will come into being with future research in this area. The only manageable way to benefit all interested parties is to centralize the holding of SNP profiles and the research being done on gene/disease associations, allowing patients to customize their access to information and then bring that information to specialists best able to counsel them on the current research in a given area.

VI. What Should Be Done With Stored SNP Profiles: A Proposed Model For The Storage And Accessibility Of SNP Profiles That Would Benefit Patients And Researchers

Infertility medicine and genetic research did not cross paths for a substantial period of time. As a result, their regulatory models developed along different paths.[210] Genetic research has long been regulated by the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and Congress.[211] By contrast, infertility medicine was explicitly pushed into the private sector, moving it out of the realm of potential NIH regulation, when Congress banned all funding to research that creates, destroys, discards or intentionally imposes risk greater than that permitted for fetuses on embryos exclusively for research purposes.[212] As a result, the regulation of infertility medicine is predominately self-regulation through professional

[210] Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations, in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 266-67 (Knowles & Kaebnick, eds., 2007).

[211] *Id.* The NIH regulates the monitoring of funds distributed for research purposes. The FDA regulates through inspections of labs and rigorous review process for new therapies and drugs. Congress regulates by setting boundaries of what is and is not an acceptable research area within the fields of "genetics," such as the ban on human cloning.

[212] Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

societies.[213] Additionally, clinics are regulated by reporting data to the Society for Assisted Reproductive Technologies (SART) which works in conjunction with the Center for Disease Control (CDC) to report on the number of cycles done and success rates by age at various clinics.[214] Clinics that do not report to SART are listed as non-reporters.[215] Clinics must also comply with FDA requirements and are subject to FDA inspections[216] as well as College of American Pathologists (CAP) inspections of the embryology and andrology labs if they seek to maintain CAP accreditation.[217]

As the fields on reproductive medicine and genetic research began to increasingly overlap, there has been a growing call for improved regulation of reproductive medicine, seemingly with the goal to bring the regulation of clinics more in line with the regulation

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[213] *See* AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM), *Practice Committee Guidelines*, http://www.asrm.org/Guidelines/ (last visited Mar. 20, 2011).

[214] SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY, *IVF Success Rates (SART)*, http://www.sart.org/frame/detail.aspx?id=3893 (last visited Mar. 20, 2011) (clinics can be searched by name or region, data is presented by age, and type of IVF cycle, success rates are reported as both pregnancy and delivery rates, CAP accreditation status is also listed).

[215] *Id*.

[216] U.S. FOOD AND DRUG ADMINISTRATION (FDA), *Inspection Guidelines*, http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm (last visited Mar. 20, 2011).

[217] COLLEGE OF AMERICAN PATHOLOGISTS (CAP), *Accreditation to the ISO 15189:2007 Standard*, http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2FpoFportl%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt%7BactionForm.contentReference%7D=laboratory_accreditation%2F15189%2Fabout.html&_state=maxmaximi&_pageLabel=cntvwr (last visited Mar. 20, 2011) (compliance with CAP is voluntary, like all other professional societies).

traditionally applied to pure genetics research.[218] However, these calls for increased regulation are very closely tied to fears of improper uses of genetic information in reproductive medicine, specifically fears of the creation of "designer babies."[219] These fears are unfounded for three reasons. First, it is highly unlikely that people would go through the expense and physical rigors of IVF if they were not infertile or seeking to avoid passing on a dangerous gene combination.[220] Second, the technology to both know the gene locations of complex traits and to successfully perform knockouts is far beyond anything we can imagine at this point.[221] Conceding that this may, although it is unlikely, change in the future, the inefficiency of human reproduction combined with the mathematics of needing a supply of embryos that no woman would be able to produce in order to select for complex traits makes the creation of designed babies an impossible task.[222] Given the unlikelihood of "designer babies" ever being a realistic cause for concern or

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[218] Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations, in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 266-67 (Knowles & Kaebnick, eds., 2007).

[219] *Id.* The creation of "designer babies" is included in a long list of potential "abuses" of genetic technology in reproductive medicine. The list also includes practices that the international community has acknowledged to be questionable (sex selection for non-medical purposes and HLA matching to create "savior siblings") but which have not been universally banned.

[220] John C. Robertson, *Commerce and Regulation in the Assisted Reproductive Industry, in* BABY MARKETS: MONEY AND THE NEW POLITICS OF CREATING FAMILIES 200-01 (Michele Bratcher Goodwin, ed., 2010).

[221] *Id*. at 193.

[222] Assuming the polygenomic trait sought is controlled by 10 genes and each gene has only 2 potential nucleic acids that can be present at that site and each gene must have the exactly correct nucleic acid in that position to obtain the desired result. In this case (and a 10 gene trait is an extremely conservative estimate for most complex traits such as height), there would be a 1/1024 chance of getting all of the genes correct in each parent (which presumes the possibility of each parent having the potential to produce the desired genes), which results in the combination of the two parents producing an embryo with each gene correct in the correct position in less than 1/1,000,000 embryos. Given that the reproductive competence of young (<30 year old) patients

reason for regulation of clinics, the option for continuing the self-regulatory model remains preferable.

The national regulatory models in place in the United Kingdom and Canada simply cannot be practically applied to the U.S., in spite of the fact that they may seem to work well there. The U.S. has a very different mindset about healthcare in general than the UK or Canada, which are much more accustomed to nationalized medicine.[223] The U.S. relies on other systems of law, namely consumer protection and tort, to keep the healthcare market in check.[224] Consumer protection and education is accomplished through reporting to SART, the CDC, the FDA and CAP accreditation. Tort liabilities, though not yet applied in the context of SNP profiles, have been applied to cases involving reproductive genetics.[225] Perhaps most significantly, the U.S. has developed a culture of belief in the concept of individual rights that has strong connections to decisions about medical care generally and specifically choices about pregnancy.[226] While it is reasonable to acknowledge the taint of eugenics in a discussion about medical genetics and clinical applications the issues that medical genetics address today are far

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is on average 1/3, the patients would need over 3 million embryos to find the desired trait perfectly coded. Furthermore, prenatal and early childhood environments are known to impact the expression of genes, creating a situation where even the exactly desired genotype may not produce the desired phenotype.

[223] Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations, in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 226-29 (Knowles & Kaebnick, eds., 2007).

[224] *Id*.

[225] *Id.*

[226] *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992); Cruzan v. Dir. Mo. Dept. of Health, 497 U.S. 261 (1990); Roe v. Wade, 410 U.S. 113 (1973); Eisenstadt v. Baird, 405 U.S. 438 (1972); Griswold v. Connecticut, 381 U.S. 479 (1965); Skinner v. Oklahoma *ex rel*. Williamson, 316 U.S. 535 (1942).

more comparable to those that are addressed through prenatal screenings than the history of eugenics.[227] Individuals have the option of obtaining a pregnancy, testing the fetus for carrier status of a known genetic illness and potentially terminating or creating embryos and making decisions about which embryos to transfer based on their carrier status. If the first choice is fully protected, there is no reason why the second option should not be equally protected, especially because embryos have traditionally held a status between person and property in the law, but have generally been characterized as closer to property.[228]

The importation of a nationalized model of clinic regulation would likely be problematic for our culture rooted in individual rights. Furthermore, the nationalized models fail to take into account the need for customized medical decisions that are required in treating infertility patients. For example, the UK's structure prohibits the transfer for more than two embryos in any given IVF cycle.[229] However, the decision of how many embryos to transfer is personal and must be closely tailored to the individual patient's circumstances and history. ASRM also makes the recommendation of a two embryo transfer as the standard of care, but leaves open the option for the physician to make a different plan if the circumstances warrant it.[230] For example, in a 44

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[227] Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations, in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 3-15 (Knowles & Kaebnick, eds., 2007).

[228] Davis v. Davis, 842 S.W.2d 588, 596-97 (Tenn. 1992).

[229] Human Fertilisation and Embryology Bill, 1990, c. 37 (Eng.) (modification in 2004 limited transfers to two embryos in women under 40); *see also* ONE AT A TIME, *Europe*, http://www.oneatatime.org.uk/372.htm#10 (last visited Mar. 26, 2011).

[230] ASRM: GUIDELINE ON THE NUMBER OF EMBRYOS TRANSFERRED (2008), http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Guidelines_and_Minimum_Standards/Guidelines_on_number_of_embryos(1).pdf (last visited Mar. 20, 2011) (note: 2008 is not the first year these guidelines were in place, but the last time of guideline document was updated).

year old patient with four poor quality embryos, a physician is likely to recommend that all four be transferred because, given the patient's age, delivery rates remain below five percent. This practice would be impermissible in the UK. Perhaps even more problematic is that regulations in some countries have only increased traveling across national borders to seek care that is prohibited in one's home country.[231] These cases are not about seeking less expensive treatment, which is an entirely different type of reproductive tourism, and are exclusively about seeking access to treatment that the patient simply cannot get at home.

The primary drawback of self-regulating bodies is that they lack police power to enforce their guidelines or rules. However, consumer protection and education can effectively create the same effect through patients not seeking treatment at clinics that refuse to conform to ASRM standards, fail to report to SART, or lack CAP accreditation. Many patients do shop for a clinic based on reputation of the facility and the doctor. Improving patients' understanding of what qualities they should look for in a clinic could substantially improve the overall quality of clinics because those that did not conform would not have the patient population necessary to sustain the clinic. I would not recommend that any of the current outside regulations (such as the FDA) be lifted because they serve an important role in making determination of safety in terms of transmission of infectious diseases. Nor am I seeking to specifically address the issues of national level regulation of third party reproduction, which generate complicated scenarios, a full discussion of which is outside the scope of this note.[232] When I claim that clinics should be able

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[231] VISIT AND CARE, *Infertility Treatments in USA*, http://www.visitandcare.com/infertility-treatment-abroad/guides/in-usa (last visited Mar. 28, 2011).

[232] Furthermore, most of the calls of regulation of third party reproduction are of the lawyers that prepare contracts for gestational carriers, donors and intended parents as well as the agencies that recruit them. These calls for regulation seek to contain the forum shopping that goes on when

to continue to self-regulate, I am referring only to the actions of the physicians that take place within the clinics.

In spite of the fact that I believe that professional societies remain the most desirable form of regulation of infertility medicine, SNP profile collection looks somewhat different. This process continues to straddle the line between genetic research and infertility medicine; however, the most compelling argument for placing SNP profiles in a centralized location is that both researchers and patients would benefit from a centralized organization of SNP data. SNP profiles should be published openly with an organization housed within the NIH, which would benefit all parties involved and improve access to the profiles, thereby furthering scientific inquiry in this area. Additionally, all research being done on gene/disease associations would be processed through the same centralized location, consolidating the data and making the central organization as use-friendly as possible for both researchers and patients seeking to gain benefits from the collection of their SNP profiles.

The scientists that have created SNP profiles and are currently holding them would benefit from a centralized placement because it would allow them to make the profiles available to patients and not carry the burden of interpreting the results. Since the doctors creating these profiles are largely reproductive endocrinologists, they are ill equipped to discuss risk ratios of heart disease or pancreatic cancer with a patient. However, as the party that creates and holds the SNP profiles, there is a very real potential liability in being unable to counsel on the risks that can be discerned from the profile.[233] A centralized holding of SNP data would give scientists an

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intended parents select a gestational carrier. These regulatory measures are generally not seeking to regulate clinics themselves.

[233] *See supra* Section V.

unprecedentedly enormous amount of data to use in furthering their work on gene/disease associations, which would, in turn, benefit the larger community. Given the sheer number of genes and diseases, an enormous data pool is needed to document actual trends that can be used to benefit patients. Increased benefits would ideally make patients more likely to contribute SNP profiles to the bank, improving the data pool available.

Furthermore, SNP profiles and increased risks for disease are a very hot area of research and continue to generate new data daily.[234] Requiring reproductive endocrinologists to keep up on that research and make counseling about risk factors available to patients for themselves, their expectant children or their frozen embryos is impractical. However, if their information was available to them in a central repository, then they could take the information to any doctor that they were seeing for counseling and could set up alerts to be notified when new research came out that was relevant to them given their SNP profile. This would limit the liability of researchers who created SNP profiles and DNA fingerprints and never intended them to be used in the counseling of disease risk ratios while allowing the patients to access as much or as little information as they want about their disease risk ratios.

Centralizing the research produced on gene/disease associations would also have profound benefits to patients. Researchers would submit new studies to the SNP repository for confirmation of the rigor of the methodology used and the validity of the claimed results. An independent panel within the repository will then be able to review the research and determine whether or not it was properly done to make notification to patients with the given SNP profile reasonable. Furthermore, the panel can classify the nature of the research to make the results more understandable to the patient. If the study is the first of its kind but seems to indicate a

[234] *See supra* note 12 and accompanying text.

strong relationship between the genes and the disease, the panel can denote that to patients. If the study is a large-scale study further confirming research that had already been performed, the panel could indicate the association to be well-confirmed. This would ensure that the research being used to educate patients about the meaning of their SNP profiles is properly reviewed for relevancy and validity.

A centralized location of SNP profiles would allow patients to control their own access, which is consistent with how we have traditionally offered genetic counseling and testing as well as prenatal testing. We do not force any patient to undergo genetic testing or counseling. Additionally, patients can chose which tests to undergo. Similarly, if the SNP bank were set up with alerts that could be customized, a patient could elect to be informed only of increased risk ratios of illnesses that have a lifestyle component, such as heart disease. Patients could also customize their alerts based on how well validated the association is. For example, a patient may want to only know about research that the independent review panel deems to be highly influential and well-performed. If profiles were only held by infertility clinics, not only would patients access to the potential information available through their profile be limited, but it would be considerably more difficult for them to be able to control what information is or is not made available to them.

The creation of the centralized SNP bank envisioned here would certainly draw the best geneticists and molecular biologists together to collaborate on research. The pool of data available to them would be unparalleled. This would certainly advance the science of linking SNP profiles to diseases and, in turn, benefit patients. Patients may be reluctant to contribute genetic information to such a large scale research project, but the samples would be de-identified to the best extent possible. More importantly, if the public understood the importance and

societal benefits of this type of project, they could potentially be more interested in participating.[235] While, as a nation, we have not traditionally had an overtly altruistic approach to the advancement of medical science,[236] proper education of the public about the vast benefits that are directly connected to increased participation could make a compelling case. Additionally, courts have consistently recognized the advancement of science as an important goal of genetic research,[237] suggesting that they would likely support a central SNP bank because of its potential public benefit and the contributions to the advancement of science.

There are some potential concerns that should be considered in relation to a centralized SNP bank; however, none of them outweigh the benefits of a centralized SNP repository. Firstly, as discussed in Section V,[238] there is the real possibility that liability could flow from misdiagnosis or failure to diagnose increased likelihood of illness based on a SNP profile. If SNP profiles were held in a central, government funded repository, issues of liability become slightly more complex. Arguably, the physician who created the SNP profile might still be liable for mischaracterization of the SNP profiles. However, it would make more sense to clearly define the liabilities of all parties involved in the statute that creates the SNP repository. The liability of the physicians that create the profiles should be limited to intentionally dispersing incorrect information. The process of documenting a SNP profile is still rooted in research and not clinical practice. Patients should be advised that the information is as correct as current

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[235] *See* George J. Annas, *Rules for Research On Human Genetic Variation- Lessons From Iceland*, 342 N. ENGL. MED. J. 24, 1830-33 (2000).

[236] *See Moore*, 51 Cal. 3d at 120.

[237] *Id*. at 140.

[238] *See Andalon*, 162 Cal. App. 3d at 600.

science allows it to be, but that it is not assured to be 100% accurate. Furthermore, SNP profile information provides only risk ratios and not definitive diagnoses. Making physician/researchers liable for SNP profiles made and distributed in good faith would substantially stifle the progress of scientific research and development in this very promising area of biogenetics.

Instead of allowing claims against the SNP repository through potentially available statutes,[239] liability should be clearly defined within the statute governing the SNP repository and limited to the liabilities outlined. Since the overarching purpose of the repository would be both to provide benefits to patients about their genetic risk factors and in exchange, they would provide DNA data to researchers, the interests of furthering scientific inquiry are significant. Patients must be made aware that their SNP profiles provide only risk ratios and the information about their risk must be considered in the context of their own personal lifestyle and circumstances. As such, they must be encouraged not to attempt to interpret the SNP profile and the related research on disease risk alone, but to seek out the counsel of geneticists or specialists that can counsel them appropriately. The SNP repository and the opportunity for customized alerts of relevant research data are not meant to replace a rapport with a physician who will give advice tailored to the circumstances of the individual. While one option is to have patients sign an acknowledgement of this fact when participating in the repository, the waiver would undoubtedly resemble an adhesion contract and may not suffice in court. The statute should make clear that the repository is only a supplement to the patient's current healthcare plan, not a substitute, and then limit liability to gross negligence or intentional intent to defraud. Courts would be bound by the language of the statute in considering liability. Limiting liability to intent

[239] *See* Federal Tort Claims Act, 28 U.S.C. §§1346(b), 2671-2680 (2007); Americans with Disabilities Act, 42 U.S.C. §§ 12101 et seq. (2009); Civil Rights Act of 1964, 88 Pub. L. 352, 78 Stat. 241 (codified in scattered sections of 42 U.S.C.) (2006).

would balance the interests of patients by giving them recourse if there is truly, intentionally neglectful action, but would grant adequate protection to researchers as to not inhibit the progress of science.

The next potential issue with the SNP repository is whether it runs afoul with the Dickey-Wicker Amendment,[240] which has been interpreted broadly to ban the use of federal funds for any research on embryos. The Dickey-Wicker Amendment is the primary reason why the research that goes on at infertility clinics takes place in the private rather than public realm, resulting in decreased governmental ability to control or regulate.[241] However, the creation of a SNP repository does not involve the creation or destruction of embryos for research purposes. Embryos in infertility clinics are created for procreative purposes and SNP profiles on them may be used to make decisions about which embryos to transfer, but does not involve the destruction of embryos for research purposes.

SNP profiles on embryos could potentially exist outside of the Dickey-Wicker ban under a Fourteenth Amendment substantive due process claim to privacy.[242] A woman's decision to terminate her pregnancy remains protected, subject to the undue burden test.[243] Most women who undergo late terminations of their pregnancies do so because of genetic abnormalities[244] and

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[240] *See* Balanced Budget Downpayment Act, I, Pub. L. No 104-99, § 128, 110 Stat. 26, 34 (1996).

[241] Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations, in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 80 (Knowles & Kaebnick, eds., 2007).

[242] *See Griswold*, 381 U.S. 479; *Eisenstadt*, 405 U.S. 438; *Roe*, 410 U.S. 113.

[243] *Casey*, 505 U.S. at 875-76.

[244] Gonzalez v. Carhart, 550 U.S. 124, 173, n.3 (2007) (Ginsberg, J., dissenting).

this decision remains protected, although the type of termination procedure available to them has been restricted.[245] If a woman could elect to terminate her pregnancy because of genetic abnormality, then her right to elect not to transfer an embryo determined to carry a genetic illness or abnormality would also be protected. However, this does not assure that federal money would be available for this use.

The surest option to avoid SNP banks conflicting with Dickey-Wicker is to report information to the repository exclusively from embryos that have been gestated. However, this would limit the information available to the bank because a substantial amount of SNP profiles are on embryos that may or may not have resulted in live births. This will also restrict the information available to parents to that which the infertility clinic can provide about the genetic composition of the embryo. Making additional information available through the repository will not increase the likelihood of seeking "designer babies" because parents are only making selection decisions based on the embryos available to them, they are not seeking (and are not able) to alter the genetic composition of their embryos in any way.

Another, though perhaps less likely, option is to repeal the Dickey-Wicker Amendment entirely. The Dickey-Wicker Amendment was passed in 1995 when IVF technology was considerably newer and there was greater fear of what might come from the creation and destruction of embryos for research purposes. The creation of new stem cell lines remains controversial with varying political parties imposing or lifting bans.[246] Human cloning, both for reproductive and therapeutic purposes, has also been controversial both in the U.S. and in the

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[245] *See Carhart*, 550 U.S. at 168.

[246] *See* BBC NEWS, *Obama Ends Stem Cell Funding Ban*, http://news.bbc.co.uk/2/mobile/americas/7929690.stm (last visited Mar. 26, 2011).

international community.[247] However, there are now separate dialogues and laws that address stem cell research and human cloning such that all of these concerns do not need to be linked in one law targeted specifically at human embryos. The research uses of IVF embryos, which are created with procreative intent, are factually distinguishable from the small minority of human embryo researchers that create and destroy embryos exclusively for stem cell and/or cloning research. The vast majority of research done on human embryos currently uses embryos that were created with procreative intent, but the individuals that created them no longer wish to use them to pursue pregnancy and they make an intentional choice to donate their embryos to research with the hope of furthering science.

If Dickey-Wicker were not to be repealed, it should, at the very least, be construed more narrowly. The actual language of Dickey-Wicker bans the creation, destruction, or knowing harm of embryos for research purposes.[248] This language does not explicitly ban the use of federal funds on embryo research in most cases, because most research is done on embryos that were created for procreative purposes. Furthermore, an analysis of harm to the embryo is highly abstract. We are at a point in the technology of reproductive medicine, a point we have been able to reach only through research, where the biopsy of a five-day old embryo does not result in harm to that embryo. A belief that any medical procedure exists without some risk of harm is fictitious. Every medical procedure and medication has risks and benefits. We have established

[247] United Nations Declaration on Human Cloning G.A. Res 59/280, U.N. Doc. A/RES/59/280 (Mar. 23, 2005). There is no single US law banning cloning for fears of running afoul with constitutionally protected rights regarding choice and pregnancy. Many federal bills that have attempted to ban of restrict cloning closely link reproductive and therapeutic cloning, complicating the debate.

[248] Dickey Amendment (Dickey-Wicker Amendment), Omnibus Appropriations Act, 2009, P.L. 111-8, div. F, sec. 509, 123 Stat. 524 (2009).

a system of weighing those risks and benefits by evaluating new procedures and medications through a tiered clinical trial structure.[249] For example, any drug that will ever be approved for use in children will first have to be tested in healthy children to establish side effects, toxicity levels and safe doses. We, as a society, have established this structure so that if the medication is determined to be safe and effective, we will be able to prescribe it to children with reasonable certainty of that medication's safety and effective dose. There is clearly a risk-benefit analysis going on in this structure. Research on embryos should be considered in a similar way. No court has ever held an embryo to hold the status of "person," let alone afford an embryo greater protection that we give to children. Research on embryos should be subject to the same risk-benefit analysis. While the possibility of harm may exist, the benefit derived from the information outweighs that small risk. The systematic ban on embryo research has boxed this rapidly developing area of medical genetics into the private sector. However, at this point in the development of SNP profiles, the public and the advancement of science would benefit tremendously if the information were managed in a more centralized way, which could only be accomplished with the assistance of the federal government.

The information in SNP profiles has the real potential to reach far beyond the field of reproductive medicine. For example, SNP profiling work has found that human specific Alu markers are indicative of ethnicity.[250] There are a finite number of these markers, approximately 32, that serve as markers of various ethnicities.[251] Within a SNP profile, an individual's true

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[249] FEDERAL DRUG ADMINISTRATION, *Drug Approvals and Databases*, http://www.fda.gov/Drugs/InformationOnDrugs/default.htm (last visited Mar. 27, 2011).

[250] G. E. Novick et al., *The Use of Polymorphic Alu Insertions in Human DNA Fingerprinting*, 16 ELECTROPHORESIS 9, 1591-601 (1995).

[251] *Id*.

ethnicity can be definitively determined scientifically. People tend to self-report their ethnicity incorrectly. Whether this error is a true mistake or a preference to over-report a portion of their ethnicity over another has never been something that could be verified in a reliable way since most people make their own ethnicity assessment based on visual cues or the individual's self-report. With the ability to read Alus in the genome, an ethnicity can now be verified, but what do we do with that information?

Firstly, this could potentially create a duty for any scenario where the self-report of ethnicity has a benefit, such as a specific scholarship, for the verification of the reported ethnicity to be required. This most certainly creates additional questions into the analysis of how many Alus would have to match a single ethnicity for a person to be able to claim that ethnicity. Secondly, this could alter the way that doctors counsel patients in regards to their risk stemming from self-reported ethnicity. Many genetic illnesses are known to cluster in certain ethnic groups, but if the patient does not report that ethnicity, then there is no indication for the doctor to test the patient. If an ethnicity could be accurately determined, then a patient could be given an objective recommendation for genetic screenings based on their Alus rather than self-report. Finally, the ability to objectively determine ethnicity could create a duty for doctors to test ethnicity before counseling for genetic testing and a potential liability for not verifying the patient's self-reported ethnicity. This brief overview is not meant to be a full analysis of the duties and liabilities stemming from the ability to map Alus,[252] but simply to serve as an example of one of the many ways that SNP profiling can reach well beyond reproductive medicine. This hypothetical could easily become a reality and we need to consider the possibilities when

[252] A full discussion of this topic is outside the scope of this note.

contemplating the best methods of organization, verification, and distribution of the information contained in SNP profiles.

Conclusion

While the collection of SNP profiles may have begun in IVF clinics as validation of a research technique, the implications for the potential value of the information contained in a SNP profile has extended way beyond this use. The creation of a SNP profile serves as an excellent DNA fingerprint of an individual, marking 980,000 places where that individual differs from other individuals. This has been profoundly useful in being able to identify exactly which embryo results in a live-born child; a validation that has been instrumentally important to the field of reproductive medicine seeking to advance new laboratory techniques and confirm the efficacy of new forms of genetic testing.

SNP profiles serve as an example of the complex ways in which clinical care seeking to benefit a patient and research seeking to benefit science can intersect. The collection of SNP profiles, often done through research protocols, also raises significant questions about the informed consent process and what we should require of physicians who collect data for a single narrow purpose, but the data itself contains so much more information. The collection of genetic material implicitly begs the question of who the owner of that material is, particularly if that material proves to be especially valuable, both to science and in terms of monetary gains stemming from patents. Recent litigation has suggested that a gene sequence itself is not subject to patent protection any longer.

The collection and banking of genetic materials also creates concerns about liability. One of these liabilities is the need to protect the privacy of patients and research subjects. No current privacy law truly contemplates and considers the privacy issues created by the collection of SNP

profiles. Physicians creating and holding SNP profiles also have the potential to incur liability stemming from their limited ability to counsel patients about the meaning of their SNP profiles. While medical genetic issues have been litigated, the models available are simply not analogous to the structure of SNP profiles.

In contemplation of all the unique properties of a SNP profile that make current models of consenting, property rights in genetic material, privacy, and physician liabilities for genetic counseling inadequate, I propose a new model for collecting and interpreting SNP profiles. Nobel Prize winner George Bernard Shaw said "[s]cience...never solves a problem without creating ten more." The problem of being able to DNA fingerprint an embryo so that it can be matched to a live-born child was certainly solved by the SNP profile, but countless other potential concerns were created. We should not wait for these lurking problems to come to the surface before we acknowledge their complexities and consider the best way to manage the information. There is no reason why patients, researchers and physicians cannot all benefit from a centralized SNP repository, maximizing the information available to patients and the data available to researchers. So often in scientific research there are those that contribute to the advancement of the science and those that benefit from those advancements and their interests must be weighed against each other in a complex calculus. In a central SNP repository we could simultaneously advance science through all the benefits that come from an enormous data pool while giving patients all the benefits of the profound amount of research ongoing in this area of molecular biology.

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Alcohol Breath Testing: Is There Reasonable Doubt?

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Introduction

The Alcohol breath test (ABT), commonly known by its commercial name as the "Breathalyzer," is a device made popular in the United States and used by law enforcement agencies throughout the world to assess and determine the blood alcohol concentration (BAC) of individuals suspected of driving under the influence (DUI).[1, 2, 3] With increased popularity of the automobile in the late 19th century, traffic accidents caused by individuals driving while intoxicated became a serious problem.[4] While legislation was created making it illegal to operate a vehicle under the influence, no quantitative method existed which could assess the intoxication level of an individual. Instead, subjective field tests were used to assess drunkenness relying on identifying certain behaviors in the suspected individual. Blood tests eventually became available to determine BAC, but since drawing blood roadside from a suspected individual is not a viable option for law enforcement officials, another method was needed which could determine intoxication or BAC indirectly and in a non-invasive manner.[8]

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History of the Breathalyzer[5]

Early research in the late 20th century showed alcohol was present in the breath of individuals who were intoxicated.[6] This seminal observation has led to over a century of work aimed at demonstrating the correlation between breath alcohol concentration (BrAC) and BAC that could be used for non-invasive alcohol testing. Correlating BrAC and BAC was not as straightforward as originally anticipated, but eventually in the 1950s, the ABT was created to quantify the BrAC of an individual. However, this instrument was based on a very simple understanding of the relationship between BAC to BrAC, and there would be disagreement about this correlation for years to come.

In 1927, Emil Bogen published a seminal report in the Journal of Medical Association,[7] documenting one of the earliest attempts to measure BrAC in the scientific literature. Bogen designed an experiment to quantify the BrAC by using the redox reaction of potassium dichromate and ethanol found in the breath. He collected breath samples in a football-shaped balloon apparatus for analysis. He then bubbled this air through a hot solution of acidic potassium dichromate. Alcohol-positive samples produced a color change in the dichromate solution from orange to green. By comparing the color change to a series of standard solutions, Bogen was able to determine a crude BAC using breath analysis. His findings found that BAC and BrAC were related by a rough 1 to 2000[7] these ideas were improved and developed further shortly thereafter and published by Liljestrand and Linde.[8]

The next progress in the development of the an actual breath testing device, all of which are referred to as "Breathalyzers" for purposes of this paper and ease of reference, came in 1938, when Rolla N. Harger[9] *et al*. developed a procedure he believed could allow breath testing

shortly after a DUI suspect was arrested, making it easier for law enforcement to gather evidence for DUI prosecutions. For this testing protocol, Harger *et al*. purported that the absorption of alcohol was always rapid in individuals, and almost immediately led to the ethanol in the body being at equilibrium. Based on his research, Harger developed a device called the "Drunkometer" to allow for non-invasive testing of potentially intoxicated individuals. The device determined BAC by having the suspect fill up a balloon with air from the lungs. The balloon was then expelled into the instrument containing an acidic solution of potassium permanganate, an oxidant, like that used by Bogen. The ethanol present in the breath would undergo an oxidation reaction with the permanganate, yielding acetic acid and manganese byproducts. This reaction was accompanied by a color change in the solution from purple to brown. Depending on the extent of this color change, the level of intoxication of an individual could be approximated via breath analysis. Though the device was not quantitative, and required the operator to subjectively judge a color change in the instrument, Harger's invention was implemented in the state of Indiana, where it was used to convict DUI suspects for many years.

Widespread use of breath testing came from the Robert F. Borkenstein, a student-collaborator of Harger. The majority of Robert F. Borkenstein's contributions to the area of alcohol and law enforcement took place while he was employed by the Indiana State Police from 1936 to 1958 and was based on the findings of Harger.[10] In 1958, although Borkenstein completed a bachelor's degree through an extension program, he had no formal education in science, and no graduate level education. Regardless, Borkenstein was named chairman of Indiana University's department of police administration. In 1954, he produced the first device to be called a Breathalyzer, a device used to determine the intoxication and/or blood ethanol levels of individuals suspected of driving under the influence.[9] Borkenstein explained that the

Breathalyzer conducts the "analysis of breath [and] will reflect the concentration of alcohol in the blood going to the brain. In this respect, the concentration of alcohol in the breath will more closely reflect the condition of the subject than will the concentration in arm (venous) blood."[11] The theories used by Harger and Borkenstein to form the bases of the Drunkometer and the Breathalyzer, respectively, are the same theories that are used to support the use of the ABT in modern instruments. Although not found in the history of breath-alcohol testing, Borkenstein, after whom "The Borkenstein Institute" at www.BorkensteinInstitute.org is named, was universally regarded as a businessman peddling a device and not a scientist. The U.S. Department of Transportation (DOT) and/or the National Highway Traffic Safety Administration (NHTSA) were very vocal about this, as well as other scientists in the community. *See Appendix A, attachments obtained via months of research and archival searches, library science and research expert, Matthew Strandmark, a graduate student at the University of Indiana.*

Modern Science Applied to the Breathalyzer

Many of the theories that were used for the development of the original ABT in the early to mid-1900s are still thought to apply to modern ABT devices. In reality, as science and medicine have progressed, many of the theories used to engineer the Breathalyzer have undergone revolutionary changes and should reflect contemporary science. As a result, some of the assumptions made in engineering the original ABT device have scientifically flawed premises when analyzed by modern science. An understanding of the pulmonary system, gas exchange, and lung physiology is important and must be thoroughly considered to engineer a reliable ABT device. The pharmacokinetics (absorption, distribution, and excretion) of ethanol is no longer understood the same way as it was by the founders of the Breathalyzer and must

likewise be considered. Along the lines of the aforementioned points, the correlation of BAC to the BrAC has higher variability among individuals than original assumed, particularly when race, age, gender, and health are considered. Additionally, the conditions under which the test is administered and the conditions of the subjects are all factors that can significantly affect the measurement of BAC. Finally, interference by endogenous organic compounds, [12,13,14,15] which can register a reading on the ABT, must be accounted for when engineering an ABT. The margin of error based on the points mentioned make the ABT an unreliable method for determining impairment, and its widespread use in court and by law enforcement should be reconsidered.

Foundations of the Breathalyzer

Early attempts to understand the relationship between the quantities of alcohol consumed, BAC, and BrAC made liberal assumptions that led to an erroneous understanding of the underlying principles needed to develop the ABT. For instance, Harger's seminal publication on the Drunkometer assumed that alcohol absorption was rapid and almost immediately led to the ethanol in the body being at equilibrium[16] (*vide infra*). In support of this theory, Harger cited a laboratory study in fasting dogs were given three grams of alcohol per kilogram via a stomach tube delivering alcohol into the dogs' stomachs directly.[7a] Absorption of 50% of the alcohol took only fifteen minutes on average, at which point most the dogs were killed due to alcohol poisoning. Harger's experiments, as described, led to a device made available to law enforcement in the State of Indiana in 1938. Harger's assumptions were improperly derived from experiments with canines and bolus dosing of alcohol, and these results were extrapolated to human models without any studies on human subjects.

Further, Harger *et. al.* supported the feasibility of breath testing incorrectly based on research on drug absorption conducted by Cushny.[17] Cushny was interested in using alveolar air, the last air expelled reflecting the contents of the alveoli, to quantify the exhalation of volatile organic compounds via the lungs. He intended to assay alveolar air and correlate the value to how much of the compound was initially administered intravenously. For quantifying ethanol, Cushny used a cat as an animal model and only performed studies on a single animal subject. No follow-up studies employing a larger sample size or other animal subjects were performed. Based on Cushny's publication, Harger purported:

> "Breath may be employed for predicting the concentration of alcohol in the body. In 1910 Cushny pointed out that the distribution between the alveolar air and the blood of such volatile substances as acetone, ether and alcohol obeys Henry's law, which means that the concentration of alcohol in the blood may be predicted from the concentration in the alveolar air." [7]

This assertion by Harger *et al.*, which was made thirty years after the actual paper on the issue was published, would later become the lynchpin of the operation of the Breathalyzer and the cornerstone of breath testing and theory upon which all Breathalyzers were based.

Although Cushny's work on drug absorption was up to par for the scientific standards of the time, the conclusions drawn in his publication cannot be applied to contemporary scientific standards. Several issues arise when implementing the work of Cushny as it applies to using the Breathalyzer as a predictor of BAC. Despite Cushny's correlation of the administered intravenous dose of an organic compound with its breath ratio, the study failed to examine the blood concentration with breath alcohol. While the values may have some correlation, it is very unlikely that the two will be identical. Furthermore, Cushny limited his sample size to a single

cat as an animal model. As a result, no statistical analysis could be applied to his studies, and no correlations could be drawn from the results.

Based on Cushny's research, a ratio was established that could correlate BrAC to BAC. Developers of the Breathalyzer have assumed that BAC could be determined from this ratio by using a simple equation, BrAC x 2100 = Assumed Blood Alcohol Concentration (ABAC). The ABAC is the value displayed by the Breathalyzer and is considered to be synonymous with BAC. This calculation operates under the assumption that the alcohol in the alveolar air is at equilibrium with the blood in the venous capillary blood supplied by the pulmonary vein. The ethanol level of the breath is then measured by the Breathalyzer and presents the result, the ABAC, by software that multiplies the BrAC by 2100.[1,14] In other words, the Breathalyzer reading, or ABAC in the United States, is actually showing you 2100 times the BrAC, the origin of which will be discussed in further detail later in this paper.

The Partition Ratio

The laws in the United States purported to define the correlation between BAC and BrAC by employing the advice of the Committee on Alcohol and Other Drugs, first known as the Committee on Tests for Intoxication.[18] The committee was given the task of determining the blood-to-breath ratio to be applied on all U.S. Breathalyzers without regard to variations in human biology and numerous other factors (*vide infra*). In 1976, the committee agreed on a 2100 to 1 ratio of blood-to-breath, meaning any result read out by the Breathalyzer would be multiplied by 2100 by the software in the Breathalyzer before the results are given. This ratio of 2100 to 1 has now become known and widely referred to as the "Partition Ratio." [19]

The term "Partition Ratio"[12] is a misnomer used in the forensic community referring to the alcohol content of a person's breath compared to the alcohol content of their blood. This is presumed to be 2100 to 1, meaning the BrAC result is converted to a BAC by multiplying it by 2100. The variability between the BAC and BrAC ratio in individual subjects is large, with values ranging from 900:1 to 3700:1.[20] More recent evaluations using modern technology still demonstrate large variability in this ratio.

From a scientific perspective, "partition" is an inappropriate term since equilibrium conditions are required to apply the term. This would occur if the alcohol exchanged within the alveolus remained unchanged, however, the fact that alcohol exchanges within the airways in a dynamic sense means that equilibrium conditions do not exist. Hence "partition" does not apply to the alcohol breath test. The only appropriate term, and one that should replace "partition ratio" would be blood-to-breath ratio (BBR), meaning the ratio of the person's BAC compared to their BrAC at a given time. Regardless of the names given, the use of a standard 2100 to 1 ratio is not scientifically sound, as ratios vary from 900 to 3700 and it is impossible to determine where this ratio truly lies at the time the Breathalyzer is used.[21]

Additionally, the term "partition ratio" has been given some erroneous interpretations by State Supreme Court Judges. For example, the California Supreme Court stated: "The conversion from breath alcohol to blood alcohol is based on the chemistry principle of 'Henry's law,' which holds that there is a constant ratio between the concentration of alcohol in the blood and the concentration of alcohol in the alveolar air of the lungs."[22] The California Supreme Court may not have realized that Henry was a scientist in the early 1800s and never knew what an alveolus was, as the word did not appear in the scientific literature until the early 1900s.[23]

A variability of significant consequence is the differences between individuals and their hematocrit content. The hematocrit is the component of blood that is made up of red blood cells. Having a high hematocrit means that the water portion of the blood is lower. Men and women have different average hematocrit compositions, with women having lower hematocrit content. This variability is not accounted for by the Breathalyzer, which leads to inaccuracy across the two genders.[24] As a result, a woman and man that have equal BACs for their body weight would have a different reading on an ABT due to their variance in hematocrit.

Furthermore, the variability among the male and female population themselves is also significant. If an individual has high hematocrit, their blood water content is low. As a consequence, the alcohol content in their blood will be diluted to a lesser extent, and this will result in a higher ABT reading. In this circumstance, the partition ratio will change depending on the percent hematocrit an individual possesses. For the previously mentioned reasons, the partition ratio is inaccurate as a static figure and must be modified on a case-to-case basis to accommodate for the many variables that can influence it. Hence, a ratio of 2100:1 is not an accurate basis for estimating BAC, and hematocrit content must also be accounted for.

External and Physiological Variations

The physiology of gas exchange in the lungs precludes the accurate assay of BAC based on BrAC. The lungs are responsible for processing the transfer of oxygen, carbon dioxide, and other gases to and from the blood. This is accomplished by a series of divided tubes that maximize the surface area of the lungs. When air is inhaled, it enters the body via the mouth and/or nose, travels through the trachea, and is then split between the two lungs into the left and right bronchi. The bronchi then divide over twenty times into smaller tubes called bronchioles.

The bronchioles are connected to over 300 million small, sub-millimeter-sized air sacs called alveoli. These sacs contain small capillaries which facilitate the exchange of gases with the bloodstream. [25,26,27]

The function of the ABT is dependent on the premise that alcohol in the bloodstream exchanges into the alveoli with a predictable rate and ratio.[28] This air must then travel through over twenty dividing branches of airways before it can reach the mouth and be assayed by the ABT. The theory of ABT starts to become questionable when one asks if this ratio and rate are highly dependent on the conditions under which breath testing is conducted. If testing is conducted on a hot summer day with high humidity, does the ratio remain the same as it would if the test were conducted on a dry, cold winter night? Furthermore, does the exchange rate and ratio depend on the breathing pattern of the individual prior to administration of the ABT?

Research has shown external factors like temperature and humidity do indeed change the outcome of the ABT.[29] As air travels from the alveoli, through the many branches of airways in the lungs, alcohol can interact with the many levels of lung tissue.[30] Alcohol is extremely soluble in biological media. As a result, breath alcohol will become absorbed and released by the lung tissue as it travels from the alveoli to the mouth and into the Breathalyzer for analysis. Accounting for this exchange is not simple. The rate of ethanol exchange and partition coefficient with the lung tissue will be highly dependent on the outside air temperature, humidity, and other external conditions.[31] Breathing in cold air will cause ethanol condensation which will decrease the amount of alcohol in the gas phase and lower the measured BrAC. In contrast, breathing in warm air will encourage evaporation of alcohol and will increase the measured BrAC. Variations in humidity have a similar effect on measured BrAC.[23] Alcohol is

rapidly absorbed into the humid environment of the lungs. When a subject is placed into an overly moist environment or an overly arid one, the exchange rate changes, and can change the amount of ethanol that is expelled in the breath. The change in breath alcohol will undoubtedly affect the readout of the ABT and add an additional layer of uncertainty.

Like temperature, breathing pattern also impacts the BrAC of a given individual.[32,33] When the ABT test is administered, the individual is always asked to inhale a large breath of air and expel it as forcefully as possible into the Breathalyzer. Studies have shown that hyperventilation shortly before breath testing can cause ABT test results to drop by 11%. Likewise, taking several deep breaths prior to testing has been shown to give an erroneously high BrAC reading by 16%. Both these phenomena are attributed to changes in the air temperature, which influence the rate of ethanol exchange and partition coefficient. [1]

Variations amongst individuals can also impact the outcome of breath analysis and can create an additional level of uncertainty when employing ABT to assay intoxication. Factors like lung function, lung capacity, age, race and overall health are important variables in ABT. Other issues arise when one considers variations in BrAC as a function of the volume of exhaled air. All major ABTs are designed to measure the alcohol content after the subject has expelled a threshold volume of air called dead air. However, the BrAc as a function of exhaled volume is not static for a given individual. This can lead to significant variations and lack of reproducibility in replicated measurements for a given individual when the volume of air exhaled is changed over several consecutive trials.

Additionally, the threshold volume of exhaled air for a given instrument is a constant value, and therefore, this volume will constitute drastically different ratios of total lung volume

among subjects of varying lung sizes. The ABT will register a result as long as the volume of air expelled is between 1.1 liters to 1.5 liters, depending on the jurisdiction and the total lung capacity. The exhaled volume of air also varies based on the limitation of the individual's lungs and the effort of the person being tested, which will always vary drastically. Hence, individuals with smaller lung capacities will need to expel a larger percentage of their total lung volume to register a reading on the ABT. These variations in lung capacities are not insignificant, and can be shown to differ among age groups, race, body size, and overall health of the individual. This is problematic when considering the previously mentioned point that BrAC is not static when considered as a function of exhaled volume of air. In fact, the measured BrAC decreases as a large volume of air is expelled. Individuals with smaller lung capacities will give unusually high BrAC readings simply because they have expelled a large percentage of their total lung capacity.[34] This point alone renders the BAC an unreliable method for quantifying intoxication as it cannot account for lung size and is biased against individuals with smaller lung capacities. The variables discussed result in a margin of error in ABT testing of 50% or higher, which does not meet the required 95% to 99% level of confidence needed for criminal cases.

Pharmacokinetic Factors

An issue of particular importance with the ABT deals with the pharmacokinetics of alcohol metabolism and how it affects the BAC when compared to the BrAC as a function of time. There are typically two pharmacokinetic phases that directly impact the ABT, absorption and elimination. If there is a non-linear relationship between BAC and BrAC it is dependent on which of these two pharmacokinetic stages a subject may be in at the point of testing. This adds an additional variable to breath testing which must be accounted for. In order for ABT to be a

useful field test for intoxication, it is necessary that the relationship between BAC and BrAC be known and accounted for, regardless of the metabolic stage of the subject. Furthermore, if this relationship varies between individuals amongst the population, then the ABT cannot serve as a just means of assaying intoxication.

A study conducted by Martin *et al*. focused on establishing a correlation between venous blood alcohol concentration (vBAC), arterial blood concentration (aBAC) and BrAC among individuals given the same dose of ethanol and amongst individuals given different doses, specifically, in the absorptive phase of alcohol metabolism.[35] The absorptive phase is defined as the phase after the last drink is consumed in which BAC is rising prior to reaching the peak level (C_{max}). Martin *et al*. wanted to determine if the time it took to reach C_{max} varied within a given dosage group and amongst different dosage groups. Martin *et al*. studied over 40 male and female subjects by administering various doses of ethanol and looked at the concentration-time profiles of three types of measurements.

The vBAC, aBAC and BrAC were then assayed simultaneously at different times after alcohol was consumed, and the two values were compared as a profile for each individual tested. Additionally, these profiles were compared to other individuals tested to determine if a standard model could be applied. The results of this study demonstrated that vBAC, aBAC and BrAC had variable relationships in the absorptive phase of alcohol metabolism such that a linear relationship could not be established. In other words, a simple relationship like the partition ratio could not be used to relate the three values during the absorptive phase. Hence it would be difficult, if not impossible, to relate BrAC to BAC in the absorptive phase of alcohol metabolism across all individuals. Furthermore, Martin *et al*. found that the time to reach C_{max} varied from

half an hour to several hours for each individual, even in the same dosage group. Therefore, it would be difficult to determine if an individual has reached C_{max}, prior to which reliable breath testing cannot be conducted. The study concluded that the ABT could not be used reliably in the absorptive phase. While one could potentially obtain more accurate results when measuring the BrAC in the elimination phase, this phase can take up to several hours to be reached, and is not predictable. Furthermore, the process of waiting for an individual to reach a metabolic point is not practical in use as a field test.

Another issue addressed by Martin *et al*. as well as several other studies is that vBAC and aBAC are not equal and vary with the metabolic stage of the individual.[36] In particular, the ABT can deliver unusually high readings during the absorptive phase of alcohol metabolism. Since vBAC is associated with impairment, the ABT is believed to reflect the vBAC of an individual. However in the study conducted by Martin *et al* during the absorptive phase, aBAC was a better indicator of impairment since during this phase, arterial blood delivers alcohol to the brain. As a result, during the absorptive phase, the ABT does not reflect alcohol that is delivered to the brain and is a poor indicator of impairment. aBAC was found to exceed vBAC by more than 50% during absorption; however, vBAC was greater than aBAC during the elimination phase of metabolism. While there existed an equilibrium phase during which aBAC and vBAC were statistically equal, this study showed that this phase was short-lived and difficult to predict. During the elimination phase, this situation is reversed, such that venous blood becomes a better indicator of impairment, since this blood is delivered to the brain. The disparity between vBAC and aBAC can be attributed to several physiological factors. During absorption, arterial blood is distributed in the organs such that it is delivered to the brain more quickly than the venous blood. It was clearly shown in the Martin study that the C_{max} was directly dependent upon the initial

dosage, where those individuals who were administered a higher dosage of alcohol had a much longer absorptive phase. For this reason, determining intoxication is further complicated, and the conditions of measurement must be even more precisely defined for when relating BAC to BrAC.

Finally, an important point to consider along the lines of pharmacokinetics is a problem often referred to as retrograde extrapolation.[37] When an individual is pulled over for a potential DUI offense, there is a time span on the lines of twenty minutes to several hours between when the suspect was driving and when the actual ABT is administered. Since absorption is not instantaneous, there is a high likelihood that the individual's BAC has changed or has not reached a maximum and is still rising between the time they are pulled over and the ABT is administered. This would mean that an individual that had a BAC below the legal limit could be convicted of a DUI offense due to the lag time in measuring the BrAC. Additionally, it is difficult to account for when the last drink was consumed in order to determine the rate of absorption of an individual.

Interference Aspects

When measuring any compound using an analytical method, information about the method's specificity and susceptibility to interference is necessary. Likewise, it is necessary to quantify any background effects that may affect the measurement. The ABT, like any other analytical method, is susceptible to a variety of interferences that may skew the results obtained. A group of breathalyzers utilizes infrared spectroscopy to determine the alcohol content present in the breath. In particular, the instrument detects the methyl groups present in ethanol. Since many other organic compounds are present in the environment, and metabolites in the body

contain this functional group,[38] this type of Breathalyzer is susceptible to error whenever other organic compounds are present. One such compound is acetone, which is a metabolite found in humans. While the device can be calibrated to account for the average amount of ethanol found in the breath, diabetics have been shown to possess an elevated level of acetone in the breath.[39] Hence, diabetics would be at an unfair disadvantage when breath is tested using an infrared-based instrument and would show a BrAC that is higher than the true measurement.

Conclusion

DUI is a major, worldwide issue that can lead to property damage, injury or death. As a result, a method to assay the state of intoxication of a suspected individual is needed. However, it is still necessary that the tools used for gathering evidence for the arrest, prosecution, and conviction of suspects be accurate, just, and scientifically sound. Although the ABT has seen an evolution of over a century with many changes to its design and instrumentation, the underlying principles that form the basis of its design remain outdated and the same as the original instrument. This is problematic considering our modern understanding of the physiological processes involved in pulmonary function and the transport of alcohol in the blood to the breath. Cushny's outdated but still widely accepted assertion that partition ratio relates a constant conversion factor for BrAC to BAC has been shown to be a liberal and inaccurate assumption. It has been demonstrated that the ratio of BAC to BrAC can be influenced by a variety of factors including, age, race, gender, physical condition, and basic genetic traits with significant variability from person-to-person.[40] Although the concept of "alveolar air" has formed the basis for relating BAC to BrAc in breathalyzers, modern understanding of the pulmonary system now reveals this concept is highly simplified, and it can be demonstrated that a variety of

environmental factors can alter the efficiency of transporting alcohol from the lungs to the breath. Additionally, pharmacokinetic factors play a non-trivial role in determining how well a Breathalyzer will relate BAC to BrAC. This relationship has been demonstrated to be highly variable and particularly influenced on the pharmacokinetic stage (absorption versus elimination) of the subject.[41] Finally, interference by exogenous substances has been demonstrated to elevate ABT readings based both on metabolites found in individuals and environmental compounds.[42]

Ultimately, the ABT does not provide reliable evidence as to the state of impairment of an individual suspected of driving under the influence of alcohol, and therefore its use as evidence in a DWI court case should be reconsidered. For the same reasons, probable cause for a blood test cannot be established by an ABT due to the variety of factors that cannot be corrected for by an officer in the field. It is the duty of those involved in the forensic sciences and the legal system to acknowledge these limitations to avoid unjustified arrests, prosecution, and conviction of innocent citizens.

Instead of utilizing an unreliable device based on outdated theory as a solution to a pressing problem, efforts should be focused on developing a non-invasive field test that can better assess the relevant signs of intoxication and provide a quantitative assessment with minimal error. This way, countless government dollars are not wasted on prosecutors that are given the burden of upholding the validity of an invalid means of measuring intoxication. Furthermore, development of better field tests would avoid the wrongful conviction of innocent individuals. Until such a device is available, prosecution should limit their reliance on the ABT as evidence for the conviction of individuals accused of drunk driving.

[1] Hlastala, M. P., 55 .J FORENSIC SCI. 451 (2010); Hlastala, M. P,. 93 J. APPL. PHYSIOL. 405 (2002); Hlastala, M. P., 84 J. APPL. PHYSIOL. 401 (1998).

[2] Dubowski, K. M., *Breath Analysis as a Technique in Clinical Chemistry,* 20.8 CLINICAL CHEM. 966 (1974).

[3] Kurt M. Dubowski, *Absorption, Distribution and Elimination of Alcohol: Highway Safety Aspects*, 10 J. STUD. ALCOHOL SUPPLEMENT 98 (1985).

[4] Linda J. Rosen & Catherine L. Lee, *Acute and Chronic Effects of Alcohol Use on Organizational Processes in Memory*, 85 J. ABNORMAL PSYCHOL. 309 (1976); N.G. Flanagan, P.W. Strike, C.J. Rigby & G.K. Lochridge, *The Effects of Law Doses of Alcohol on Driving Performance*, 23 MED. SCI. LAW 203 (1983).

[5] The word "Breathalyzer" is a trademarked term for the breath-testing instrument developed by Robert Borkenstein in 1954. It was not a generic term for all breath-alcohol analyzers at the time, but for purposes of modern day terminology and this paper, it is used as a generic term.

[6] Arthur D. Baldwin, *Anstie's Alcohol Limit*, 67 AM. J. PUB. HEALTH 679, 679 (1977).

[7] Emil Bogen, *Drunkenness: A Quantitative Study of Acute Alcoholic Intoxication*, 89 J. AM. MED. ASS'N 18, 1508 (1927).

[8] Dubowski, *supra* note 3.

[9] R.N. Harger, E.B. Lamb, and H.R. Hulpieu, *A Rapid Chemical Test for Intoxication Employing Breath: A New Reagent for Alcohol and a Procedure for Estimating the Concentration of Alcohol in the Body from the Ratio of Alcohol to Carbon Dioxide in the Breath*, 110 J. AM. MED. ASS'N. 11, 799 (1938); R.N. Harger, R.B. Forney, and H.B. Barnes, Estimation of the Level of Blood Alcohol from Analysis of Breath, 36 J. LAB. & CLINICAL MED. 306 (1950).

[10] Lucas, DM, Professor Robert F. Borkenstein - *An Appreciation of His Life and Work*, Centre of Forensic Sciences Toronto, Ontario Canada, Central Police University, Central Police University Press. http://www.borkensteincourse.org/borkenstein_appreciation.pdf (last visited June 27, 2012).

[11] Robert F. Borkenstein & H. W. Smith, *The Breathalyzer and Its Application*, 1 MED. SCI. LAW, 13, 13 (1961).

[12] Wolfram Miekisch et al., *Diagnostic potential of breath analysis—focus on volatile organic compounds*, 347 CLIN. CHEM. 25, 25-39 (2004).

[13] Miekisch W. Schubert, Schubert JK, Noeldge-Schomburg GF, *Diagnostic Potential of Breath Analysis—Focus on Volatile Organic Compounds,* Clinica Chimica Acta; International Journal of Clinical Chemistry, 347(1-2); 25-29 (2004).

[14] Kurt M. Dubowski et al., *Response of Breath-Alcohol Analyzers to Acetone: Further Studies*, 8 J. OF ANALYTICAL TOXICOLOGY 205, 205 (1984).

[15] CM Bell & SJ Gutowski, *Diethyl Ether Interference with Infrared Breath Analysis*, 16 Journal of Analytical Toxicology 166 – 68 (May-June 1992).

[16] Okorie Okorocha, *Commentary on: Sterling K. The rate of dissipation of mouth alcohol in alcohol positive subjects*, 57 J Forensic Sci. 1140 (2012).

[17] Arthur R. Cushny, *On The Exhalation of Drugs By Lungs*, *in* The Journal of Physiology, 17 (40th ed., 1910).

[18] http://www.nsc.org/get_involved/divisions/Pages/CAODwebpage.aspx, (accessed on July 20, 2012, 4:00pm).

[19] This ratio is written into many state laws, including California, as follows: "A breath alcohol concentration shall be converted to an equivalent blood alcohol concentration by a calculation based on the relationship: the amount of alcohol in 2,100 milliliters of alveolar breath is equivalent to the amount of alcohol in 1 milliliter of blood." (Cal. Code Regs., tit. 17, § 1220.4, subd. (f)).

[20] Alobaidi, T. A. A.; Hill, D. W.; Payne, J. P. BR. MED. J. 1479 (1976); Brugsch, J.; Fink, H; Fromm, H.; Haberzeth, W. ZSCHR. INN MED. 647 (1959).

[21] Mason, M. F.; Dubowski, K.M., 21 J. FORENSIC SCI. 21 (1976).

[22] People v. McNeal, 46 Cal.4th 1183, 1191(2009).

[23] Debora M.Olkon, Joannides Minas. The capillary Circulation in the Alveolus Pulmonalis of the Living Dog. *45* ARCHS. INTERN. MED *201-205* (1930).

[24] Labianca, D. A., 67 J. CHEM. EDUC., 259 (1990).

[25] R.W. Glenny, & H.T. Robertson, *Regional Differences in the Lung*., *in Complexity in Structure and Function of the Lung* (Michael P. Hlasta & H.T. Robertson eds., 1998).

[26] Michael P. Hlastala & Albert J. Berger, Physiology of Respiration 28 (2nd ed. 1996).

[27] Michael Hlastala et al., INFORMA HEALTHCARE, COMPLEXITY IN STRUCTURE AND FUNCTION OF THE LUNG, (1998 ed.).

[28] Edward F. Fitzgerald, Intoxication Test Evidence Ch. 29 (2nd ed. 2011).

[29]Joseph C. Anderson, Michael P. Hlastala, *Breath Tests and Airway Gas Exchange,* 20 PULM. PHARMOCOL. THER. 112, (2010) (discussing the theory of airway breath tests). .

[30] Michael P. Hlastala, *Paradigm Shift for the Alcohol Breath Test*, J. FORENSIC SCI. 451 (2010).

[31] A. W. Jones, *Effects of Temperature and Humidity of Inhaled Air on the Concentration of Ethanol in a Man's Exhaled Breath*, 63 CLINICAL SCI. 441, 441-445 (Gr. Brit. 1982).

[32] A. W. Jones, *Role of Rebreathing in Determination of the Blood-Breath Ratio of Expired Ethanol*, 55 JOURNAL OF APPLIED SCI. 1237, 1237-1241 (1983).

[33] Hlastala, M. P.; Anderson, J. C., *35* ANN. BIOMED. ENG. 264 (2007).

[34] Hlastala, M. P., 23 DWI JOURNAL: LAW & SCIEN*CE* 11(2008).

[35] E. Martin, W. Moll, P. Schmid & L. Dettli, *The Pharmacokinetics of Alcohol in Human Breath, Venous and Arterial Blood After Oral Ingestion*, 26 EUR. J. OF CLINICAL PHARMACOLOGY 619, 619 (1984).

[36] G. Simpson, *Accuracy and Precision of Breath Alcohol Measurements for Subjects in the Absorptive State*, 33 CLINICAL CHEMISTRY 753, 755 (1987).

[37] Douglas Posey & Ashraf Mozayani, *The Estimation of Blood Alcohol Concentration*, 3 FORENSIC SCI. MED. PATHOL. 33 (2007).

[38] J.P. Conkle, B.J. Camp, B.E. Welch, 30 ARCH. ENVIRON. HEALTH 290 (1975); B. Krotoszynski, G. Gabriel, Claudlo O'Neill, M. P., 15 A. J. CHROMATOGR. SCI. 239 (1977).

[39] Tazhmoye V. Crawford, Donovan A. McGrowder & Joan M. Rawlins, *An Assessment of Falsely Convicted Type 1 Diabetics in Jamaica by Using the Breathalyzer Test*, 5 J. CLINICAL & DIAGNOSTIC RES. 448, 448 (2011), *available at* http://www.jcdr.net/articles/PDF/1306/2268.pdf.

[40] Michael P. Hlastala, *Paradigm Shift for the Alcohol Breath Test*, 55 J. FORENSIC SCI. 451, 451 (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1556-4029.2009.01269.x/pdf.

[41] Okorie Okorocha, Commentary On: Sterling K. The Rate Of Dissipation Of Mouth Alcohol In Alcohol Positive Subjects, J Forensic Sci 2012.

[42] Amanda Bolduc, *Breath Alcohol Testing Instrument Performance Reviews*, https://outside.vermont.gov/dept/VTProsecutors/Shared%20Documents/DataMaster%20DMT%20Discovery/DMT_CERT_Pre-Deployment_Testing/DMT%20Testing/Testing%20results/Breath%20Alcohol%20Tester%20Performance%20Reviews.pdf.

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Forensic Science in Court: Challenges in the Twenty-First Century

Pete Frick[1]

Citation: DONALD E. SHELTON, FORENSIC SCIENCE IN COURT: CHALLENGES IN THE TWENTY-FIRST CENTURY (2011).

Relevant Legal and Academic Areas: Forensic Science, Criminal Law, Evidence.

Summary: *Forensic Science in Court: Challenges in the Twenty-First Century* is a book that explores the legal implications of forensic science. Starting with the history of scientific evidence in court, the book progresses into an examination of how courts treat current types of forensic evidence, specifically how modern juries receive and weigh forensic evidence, and how judges determine what evidence can be allowed. Judge Shelton makes good use of case studies in the book to illustrate the academic points in a real-world setting.[2]

About the Author: The Hon. Donald E. Shelton is an active trial judge with over twenty years of experience on the bench. In addition to his law degree, Judge Shelton has master's degrees in both criminal justice and criminology and is one of only seven American judges with a Ph.D. in judicial studies. Judge Shelton is also an adjunct professor at Eastern Michigan University, teaching classes in both criminology and political science.[3]

Introduction

The introduction lays out a roadmap for the progression of the book, but also establishes several important background ideas. Shelton makes sure the reader understands that testimony from scientific experts is a form of expert testimony, designed to allow opinion testimony to

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[2] DONALD E. SHELTON, FORENSIC SCIENCE IN COURT: CHALLENGES IN THE TWENTY-FIRST CENTURY (2011).

[3] *Id.* at 183.

reach the jury that would be precluded if offered from a lay witness.[4] The basic questions that forensic testimony is designed to address are "who", "whether", and "how."[5] Scientific testimony is allowed by trial judges based on either the *Daubert* test or *Frye* test, and not only must forensic science methods be examined under these tests for viability, advanced technology has created possible constitutional questions to admissibility of evidence as well.[6]

The History and Development of Scientific Evidence

U.S. courts have been accepting expert scientific testimony and evidence for well over a century, and established a pattern of routine acceptance of expert witnesses offered by the prosecution.[7] Case law developed into a self-perpetuating standard with the advent of the *Frye* doctrine, which required merely that testimony be "generally accepted."[8] Courts would use admissibility by other courts as evidence that the field or idea was becoming more "generally accepted" and the defense rarely challenged prosecution-generated forensic evidence empirically or for scientific reliability.[9]

Prosecution witnesses were allowed to give identification testimony, not in terms of probability, but as a "match" or even "unique match" despite the fact that the experts were often

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[4] SHELTON, *supra* note 2, at 1.

[5] *Id.*

[6] *Id.*

[7] *Id.* at 9.

[8] SHELTON, *supra* note 2, at 9.

[9] *Id.*

criminal investigators with little or no scientific training.[10] In addition, experts in other scientific areas were allowed to testify to conclusions about the origin of materials used in a crime. Social scientists were allowed, by courts, to give opinion testimony that a complainant's conduct was consistent with other persons who had been abused in a similar manner to the complainant's claim in order to "prove" that the complainant was telling the truth.[11]

Thankfully, the immergence of DNA evidence and new fingerprinting technologies has led courts to question the validity of older scientific methods that were generally accepted such as comparative bullet lead analysis, tool-mark testimony, serology testing, and hair and fiber analysis.[12] Of the first two hundred post-conviction DNA exonerations, 22 percent were based on false hair or fiber comparisons, and almost 40 percent were based on serology evidence.[13] These exonerations are "undisputable proof of the 'documented ills' of other forms of scientific evidence, including such traditionally admitted forms of evidence as fingerprints."[14]

The Problem of Junk Science: Frye and the Daubert Trilogy

The trial judge is firmly entrenched as the gatekeeper that determines which forms of scientific forensic evidence are "appropriate for consideration by the jury" in all U.S. jurisdiction.[15] While some states still use the test established in *Frye v. United States*, the

[10] SHELTON, *supra* note 2, at 9.

[11] *Id.*

[12] *Id.* at 12.

[13] *Id.*

[14] SHELTON, *supra* note 2, at 12.

[15] *Id.* at 17

majority of states and the Federal courts have adopted a revised admissibility standard articulated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, and later modified by *General Electric Co. v. Joiner* and *Kumho Tire Co. v. Carmichael*.[16] While the *Frye* test was whether the method was "generally accepted" the Court ruled in *Daubert* that the criteria for determining admissibility should include whether the theory had been tested, whether it "has been subjected to peer review," its error rate, whether its operation was controlled by standards, and whether it is accepted within the relevant scientific community.[17] In *Joiner*, the Court indicated that the trial judge can disallow expert opinion, even if it is based on accepted methodology if the conclusion is not reliably based on that methodology, and in *Kumho*, the Court held that the *Daubert* test should be applied for all experts, not just scientists.[18] It is unclear if these standards are rigorously applied to prosecution witnesses however, and a congressionally authorized study concluded that "the existing legal regime – including the rules governing the admissibility . . . and judges and lawyers who often lack the scientific expertise necessary to comprehend and evaluate forensic science – is inadequate to the task of curing the documented ills of the forensic science disciplines."[19]

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[16] SHELTON, *supra* note 2, at 17.

[17] *Id.* at 17-18.

[18] *Id.* at 18.

[19] *Id.* at 19.

DNA: The New Gold Standard

DNA evidence is the "gold standard" of forensic evidence because it is very durable, can be extracted from small remains long after a crime, is "polymorphic,"[20] and is precise enough to "often demonstrate that only one person in billions could have been the source of the specimen evidence."[21] The first successful use of DNA in a U.S. criminal prosecution was in *Andrews v. State*, a rape case, and since that time DNA evidence has become admissible in virtually every jurisdiction.[22] DNA evidence has almost totally replaced blood typing for identification and is "the most important forensic science development of the twentieth century."[23]

The three common methods to generate DNA profiles are restriction fragment length polymorphism, polymerase chain reaction (PCR), and short tandem repeats tests.[24] PCR-based DNA evidence has been specifically admitted in more than thirty-five states and is the last common form of DNA profile to have any questions to its validity.[25] Absent fraud or error in handling, the probability of a false positive result is miniscule.[26]

DNA evidence has value beyond proving identity. Prosecutors are urged to use DNA evidence "just as any other form of evidence – to corroborate, validate and/or impeach evidence

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[20] SHELTON, *supra* note 2, at 27 (meaning that DNA is unique among humans and, with the proper method for extraction, can identify the donor of the specimen with overwhelming accuracy).

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] SHELTON, *supra* note 2, at 28.

[25] *Id.*

[26] *Id.*

or testimony."[27] Despite DNA profiling being scientifically superior, , it is not infallible. Human error can always cause invalid results and DNA evidence has been recently challenged on many factors including: poor laboratory proficiency in testing, lack of proper lab protocols, lack of quality control, and broken custody chains. In addition, DNA is very sensitive to environmental conditions and can "start to degrade depending on the sample's exposure to extreme temperatures, oxygen, water, sweat, and breath."[28] However, the biggest threat to the use of DNA in criminal trials may come from the immense demand by police and prosecutors. This overwhelming demand may be resulting in poor laboratory practices and the hiring of inexperienced or overworked technicians, which can cause the confidence in DNA results to be affected.[29] The role of judges in determining when human error is a significant risk factor in DNA results is important because a 2005 Gallup poll shows that 85% of "Americans think DNA evidence is either completely or very reliable."[30]

DNA testing is also important in the post-conviction arena. It is now up to the courts to determine when DNA testing should be used in a search for important exculpatory evidence. While courts are trying to adapt common law standards and statutes regarding post-conviction relief to DNA testing requests, the Department of Justice completed a study in 1999, concluding that out of five possible categories of DNA testing requests, the court should consider it in only two. Where "biological evidence was collected . . . still exists, [and if] subjected to DNA testing or retesting, exclusionary results will exonerate the petitioner" or "would support the petitioner's

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[27] SHELTON, *supra* note 2, at 28.

[28] *Id.* at 29.

[29] *Id.*

[30] *Id.* at 30.

claim of innocence, but reasonable persons might disagree as to whether the results are exonerative."[31]

The "Who" Question

Fingerprint analysis is the first means of forensic identification discussed by Shelton in this section. After a lengthy discussion of the different methods used to lift and compare fingerprints, the main focus is on the analysis required to determine an identifying match.[32] Particularly telling is that fingerprint examiners consider their expertise to be a matter of qualitative, not quantitative analysis. "[T]he ability to see details in prints and the ability to compare features in prints is an 'acquired skill' gained through experience and a lengthy apprenticeship."[33] Examiners believe it is impossible to establish a numerical score or threshold based on corresponding features because examiners do not determine the relevance of those features until an initial "analysis and comparison"[34] is made.

Although the determination that two different persons could not have produced the print is a subjective assessment, examiners generally refuse to use statistics to assign match probabilities and instead testify with "absolute certainty" that the prints could not possibly have come from two different individuals.[35]

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[31] SHELTON, *supra* note 2, at 30-31.

[32] *Id.* at 44.

[33] *Id.* at 46.

[34] *Id.*

[35] SHELTON, *supra* note 2, at 46.

This practice leads to serious question about the scientific value of fingerprint analysis in criminal proceedings under *Daubert*. Although the claims made by fingerprint examiners enjoy unquestioning belief among the lay public, including the bench and bar, there is little conventional science to support these generally accepted claims.[36] There is no scientific or court-recognized minimum standard for the number of points of similarity necessary to declare a fingerprint match. Summary assessments of fingerprint analysis from the National Academy of Sciences, Haber and Haber, and Professor Jennifer Mnookin all identify serious flaws in the science behind fingerprint analysis, as well as the accuracy and validity of the claims by analysts.[37] Although this information should not affect jurisdictions using a *Frye* analysis, because fingerprint analysis has been "generally accepted" for a long time, jurisdictions using a *Daubert* analysis should be radically affected. This has not been the case however; as no court has ruled to date that fingerprint analysis expert testimony cannot at least be given to the jury as a question, despite the mounting evidence that fingerprint analysis is more art than science.[38]

Handwriting analysis is tackled next by Shelton, and his analysis is quite similar the analysis of fingerprint testimony. Despite being based on the basic principle that "although individuals have variations in their own writing, no two persons write the same way", there is no identified or accepted system for analyzing handwriting and all conclusions are subjective evaluations made by the examiners.[39] Scientists have expressed concern that the basic principle above, while plausible based on intuition, has never been established through scientific evidence.

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[36] SHELTON, *supra* note 2, at 46.

[37] *Id.* at 47-48.

[38] *Id.* at 50.

[39] *Id.* at 54.

A study sponsored by the FBI succeeded in showing that a group of trained examiners was significantly better than a group of untrained college students at identifying handwriting samples, but the professionals still declared erroneous identification in 6.5% of the cases.[40] To date, courts seem reluctant to apply a *Daubert* analysis to handwriting testimony; much like fingerprint testimony, but Shelton speculates that a highly publicized conviction overturned by DNA evidence could be all it takes to change this trend.[41]

Shelton also examines hair analysis and bite-mark analysis as identifying evidence and comes to the same basic conclusions as in the previous sections. Both of these disciplines have been called into question under scientific analysis and even if they have "general acceptance" would not survive a true *Daubert* test.[42] Hair analysis has already been rejected by many courts, and bite-mark testimony, while not rejected in as many jurisdictions, has been excluded all together by some.[43]

The "How" Question

Forensic evidence is also used by prosecutors to prove the origins and mechanism of events at a crime scene. Tool mark evidence is one of the oldest of these, and consists of the impressions left when a hard tool contacts a softer object.[44] Examples include the marks left by a screwdriver or crowbar used to break into a door or window, as well as marks generated during a

[40] SHELTON, *supra* note 2, at 56.

[41] *Id.* at 57-58.

[42] *Id.* at 67-77.

[43] *Id.*

[44] SHELTON, *supra* note 2, at 81.

manufacturing process such as the groove in a barrel of a gun.[45] Firearms testimony is one of the more common forms of tool mark evidence and American courts have routinely admitted this form of expert testimony for over 130 years.[46] By comparing the markings on the bullet the groove in the barrel of a gun and the markings on the cartridge to the firing pin with a comparison microscope, experts testify that the bullet in question could only have been fired from one specific firearm.[47]

Like fingerprint and other impression testimony however, the testimony of tool mark experts is, in the final analysis, subjective. The 2009 National Academy of Sciences ("NAS") report is critical of the scientific basis for the type of tool mark and ballistic evidence that has been routinely accepted by courts because "not enough is known about the variabilities among individual tools and guns" and because "sufficient studies have no been done to understand the reliability and repeatability of the methods."[48] The report also noted the "heavy reliance on the subjective findings of examiners rather than on the rigorous quantification and analysis of sources of variability" and the lack of a "precisely defined scientific process."[49]

Despite these findings, there have been no reported cases that reject the fundamental assumption of firearm or other tool mark testimony based on a *Daubert* analysis.[50] Two recent Massachusetts cases included lengthy *Daubert* hearings regarding the admissibility of firearms

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[45] SHELTON, *supra* note 2, at 81-83.

[46] *Id.* at 84.

[47] *Id.* at 82.

[48] *Id.* at 85.

[49] SHELTON, *supra* note 2, at 85.

[50] *Id.*

testimony, but found that while the expert in the current case was not qualified, firearms testimony in general was admissible.[51]

Bullet lead comparison[52], widely used earlier in U.S. judicial history, has been almost completely rejected by every jurisdiction. The FBI has even discontinued the use of bullet lead comparison in its investigations following a 2004 NAS study that found the practice was based on faulty science.[53]

Bloodstain pattern evidence is another very common form of forensic evidence, especially conclusions drawn from the patterns of blood spattering at a crime scene.[54] Even though the practice claims to be based in "biology, physics, and mathematics" there are no formal education requirements for qualifying experts in blood pattern analysis.[55] Professional organizations, such as the International Association for Identification, which requires as little as 240 hours of workshop training for certification, and the Scientific Working Group on Bloodstain Pattern Analysis which has recognized an analyst who had "a high school diploma or equivalent and four years of job-related experience" do little to support the claimed basis.[56] A NAS report was highly critical of bloodstain pattern analysis, noting that exit wounds are highly variable due to the damage bullets cause in soft tissue and the complex patterns that fluids make.

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[51] SHELTON, *supra* note 2, at 85.

[52] *Id.* at 85 (the practice of measuring the combinations of arsenic, antimony, tin, copper, bismuth, silver, and cadmium in bullets on the theory that the batches of bullet lead have unique combinations of these elements and that two bullets with the same ratios must have come from the same source).

[53] *Id.* at 86.

[54] *Id.* at 98-100.

[55] SHELTON, *supra* note 2, at 101.

[56] *Id.*

The report stated, "[E]xtra care must be given to the way in which [bloodstain pattern analyses] are presented in court. The uncertainties associated with bloodstain pattern analysis are enormous."[57]

However, like the other historically accepted forms of forensic testimony discussed earlier, courts are reluctant to fully apply the *Daubert* test to bloodstain pattern analysis.[58] This reluctance is coupled with a general propensity to qualify experts on very minimal credentials.[59] In fact, an appellate court in Texas has even approved the qualification of a local police officer with "45-50 hours" of instruction at a conference as an expert in blood pattern analysis.

Jurors and Forensic Science Evidence

Judges' decisions about the admissibility of forensic evidence are extremely important due to the extent that jurors consider such evidence especially critical to their ultimate decision about guilt.[60] It is widely perceived that modern juries give a great deal of weight to scientific evidence.[61] Prosecutors have often complained that jurors today demand more scientific evidence and will wrongfully acquit defendants if scientific evidence is not presented. Most of the blame for this is based on popular television, and is even colloquially known as the "*CSI* effect."[62] Empirical studies of jurors conducted in 2006 and 2009 were conducted to determine

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[57] SHELTON, *supra* note 2, at 102.

[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] SHELTON, *supra* note 2, at 115.

[62] *Id.*

if juries indeed expect and demand more scientific evidence, and if so, was this demand related to television watching habits. The results confirmed that jurors do expect prosecutors to present scientific evidence; particularly in cases where the majority of evidence is circumstantial, but they also found that there was no measurable correlation between the demand for evidence and watching *CSI* or similar programming.[63]

Instead, Shelton postulates that it is not television that is shaping the jurors' desire for scientific evidence, due to the fact that television is not as influential a media source as it was in the past.[64] Shelton considers the "cultivation theory" put forward by George Gerbner over thirty years ago, but argues that due to the greater programming offerings available and the additional forms of entertainment media available, the effects of television as a shaper of reality has been diminished in force and scope.[65]

Judge Shelton identifies that the 2006 study on jurors indicated a correlation between the sophistication of technology used in the juror's everyday life and the amount of scientific evidence that they expected.[66] He proposes that instead of a "*CSI* effect," this evidence points to a general "tech effect" instead.[67] Because jurors are able to access individual GPS devices and mail-in DNA test kits for determining parentage and know that these technologies can be used in trials, expect that a complete investigation would include these elements.[68] While prosecutors

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[63] SHELTON, *supra* note 2, at 116.

[64] *Id.*

[65] *Id.* at 116-17.

[66] *Id.* at 117.

[67] SHELTON, *supra* note 2, at 117.

[68] *Id.* at 118.

argue that this trend has improperly increased their burden of proof, Shelton counters, "constitutional commitment to a jury system is a judgment that justice in individual cases *should* reflect the values of the popular culture."[69] "Jurors think that DNA and other modern scientific techniques are extremely accurate," and they are correct.[70] With the ability to declare a random-match probability of one in 7.87 trillion, jurors will find that evidence "highly probative, if not dispositive."[71] The trend of jurors demanding more scientific evidence will continue, and the government and judicial system must respond and adapt to those trends.[72]

One method being used by prosecutors to address a jury's desire for scientific evidence is to introduce evidence of tests that were not done, or tests that did not incriminate the defendant.[73] Over objection that this evidence was irrelevant, in *State v. Cooke*, Delaware Judge Herlihy ruled that juror's expectations for scientific evidence are influencing trials enough to justify the prosecutor's presentation of "negative evidence."[74] In *United States v. Fields*, the United States Court of Appeals for the Fifth Circuit upheld a ruling allowing the prosecutor to display nineteen photographs of the murder victim at the crime scene, despite the gruesome nature of the decomposing body, because they were, "highly probative based on the defense's position that there was no reliable DNA evidence and little crime scene evidence regarding the body itself." The court recognized the increased demand for scientific evidence by modern jurors and allowed

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[69] SHELTON, *supra* note 2, at 118.

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] SHELTON, *supra* note 2, at 118.

[74] *Id.* at 119.

otherwise prejudicial evidence to be admitted to explain why some scientific evidence could not be presented.[75]

Courts have also allowed attorneys to address the "tech effect" and juror expectations directly at trial during voir dire, and prosecutors have tried to expand into opening statements, and closings.[76] Shelton gives many examples of allowable voir dire questions that both directly and indirectly reverence *CSI* and scientific evidence.[77] Multiple courts have also upheld peremptory challenges in the context of a *Batson* challenge, holding that concerns over responses to "*CSI*" questions were not just pretextual and race-neutral.[78]

While judicial response to attorney's attempts to address these same issues in opening or closing arguments has been mixed, it appears to at least, be a context-based decision. Courts have held that arguments revolving around "television expectations" will not be allowed if they disparage or trivialize the actual constitutional standard of the burden of proof.[79] Jury instructions are another area where the "tech effect" may sometimes be addressed. While standards are still being determined, Shelton states, "If the trial judge gives an instruction regarding the lack of scientific evidence, . . . it should be cast in terms of reasonable doubt to make sure that the jury understands that while a lack of scientific evidence alone does not mean

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[75] SHELTON, *supra* note 2, at 119.

[76] *Id.*

[77] *Id.* at 120.

[78] *Id.* at 121.

[79] SHELTON, *supra* note 2, at 121.

there is reasonable doubt, they must . . . determine whether the government has proven, without such scientific evidence, the defendant's guilt beyond a reasonable doubt."[80]

Conclusion

The questioning of routine admission of forensic science evidence in criminal prosecutions began during an era when science and technology was experiencing a surge of development.[81] Because of the miniaturization of computers and application of computer technology to every aspect of human life, society's awareness of technology is at an all time high.[82] This technological backdrop, and the changing legal, scientific, and cultural landscape, has cast significant doubts as to the continued use of many types of previously unquestioned forensic science evidence.[83] Three events have spearheaded this movement: the Supreme Court decision in *Daubert*, the advent of DNA as a model for forensic identification, and the use of DNA to exonerate innocent individuals convicted based on erroneous forensic evidence.[84] The technological proficiency of jurors and the increased expectation for prosecutors to produce scientific evidence at trial are at odds with a move away from the legal sufficiency of forensic techniques that have been long expected. New technologies will undoubtedly fill the void created as these technologically savvy jurors recognize the scientific flaws in traditional forensic

[80] SHELTON, *supra* note 2, at 124.

[81] *Id.* at 125.

[82] *Id.* at 126.

[83] *Id.*

[84] SHELTON, *supra* note 2, at 126.

techniques, and prosecutors will be forced to move away from them until they can be scientifically proven.[85]

[85] SHELTON, *supra* note 2, at 140.

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Navigating Climate Change Policy: The Opportunities of Federalism

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Relevant Legal and Academic Areas: Environmental Science, Law, and Public Policy

Summary: Because of climate change's inherently global nature, most proposed solutions have been tailored to a global scale. *Navigating Climate Change Policy: The Opportunities of Federalism* challenges the idea that because climate change is a global issue, only actions on a worldwide scale can lead to a resolution. It considers the perspective that since climate change itself has both global and local causes and implications, the most effective policies for adapting to and mitigating climate change must involve governments and communities at many different levels. The editors and authors feel federalism is well-suited to address the challenges of climate change because it permits distinctive policy responses at a variety of scales. This book uses a variety of viewpoints and blends legal and policy analyses to provide thought-provoking coverage of how governments in a federal system can cooperate, coordinate, and accommodate one another to address climate change.

INTRODUCTION

This book takes the stance that a policy created by one level of government cannot possibly achieve an effective climate change policy because it would fail to touch on the vast variety and layers of actions and choices the area involves.[2] The book argues that federalism offers a way to create the necessary complementary policies at differing scales to better address climate change because federalism acknowledges different powers, responsibilities, interests, and

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competencies at different levels of government.[3] The contributors to this work seek to aid all three branches of local, state, and federal government in creating future climate change law by identifying the strengths of American federalism, recognizing the challenges it poses to efficient governing, and posing the possibilities it can offer for climate change policy.[4] Since climate change policy will "reveal the capacity of our political and legal systems to respond to new and immensely complex and diffuse challenges," this book aims to lay a foundation for new policy and structure how to resolve conflicts in the future.[5]

SECTION 1: Scientific Background on Climate Change

Chapter 1: Global Climate Change as a Local Phenomenon

In this chapter, a climate scientist, law professor and social scientist lay out the scientific framework of climate change and explain how it is simultaneously a global and local happening.[6] Climate change is measured as a global mean in a single global climate system since greenhouse gases combine together in the collective atmosphere, however; these gases began at an individual-produced level.[7] Geographic variations create significant differences in causes impacts and capacities for responses from place to place.[8] The most important aspect of this

[3] SCHLAGER, *supra* note 2.

[4] *Id.* at 3.

[5] *Id.* at 5.

[6] *Id.* at 3.

[7] SCHLAGER, *supra* note 2, at 9-10.

[8] *Id.* at 10.

variation is that it occurs over multiple political scales, allowing local and regional actors to influence climate change decision.[9]

Although climate change warms the planet as a whole, some areas will be affected more so and more quickly than others. The authors highlight the increased temperatures and changes in precipitation US Southwest to demonstrate how a particular location, its residents and its ecosystems may experience various climate change effects.[10] Changes in water temperature will also increase the probability of tree death and wildfire frequency, duration and season length across the West.[11] "A similar story with different emphases and impacts applies to each region, state, and watershed in the United States."[12]

The authors identified only a few implications of climate change and did not address other topics such as endangered species, disease and human health, energy use and productions, cities, or agriculture.[13] The author's objective was to illustrate how the "dramatic and varied local and regional impacts of climate change explain and justify the demand for local and regional political and policy responses."[14]

The authors refer to climate change as happening on Earth's stage. The built environment of states, cities, towns, roads and water systems serve as its "furniture," human inhabitants play its "actors," and the interaction between the two shows how global climate change occurs on a

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[9] SCHLAGER, *supra* note 2, at 10.

[10] *Id.* at 11.

[11] *Id.* at 13.

[12] *Id.*

[13] SCHLAGER, *supra* note 2, at 15.

[14] *Id.*

much smaller scale, unique to each region.[15] Relationships, such as the one between the federal government and American Indian Tribes, and events, like Hurricane Katrina, demonstrate how social factors such as poverty, race, and class affect climate change challenges.[16]

Locality influences two major approaches to climate change policy: mitigation and adaptation. The authors believe the current understanding of mitigation as solely a large scale effort is wrong. Mitigation is inherently regional because it dependent upon "regional advantages and disadvantages in both traditional and alternative energy and resource production" based upon environmental factors and social factors, such as wealth, political institutions, knowledge, industry, housing and transportation.[17] Adaptation traditionally takes place at local, state or regional levels because it requires knowledge and experience particular to the specific area much like when responding to a natural disaster.[18] However, the federal government is pivotal to cover deficits in state and local actions.[19]

The authors conclude the chapter stating it will be localities that feel firsthand and therefore respond to the effects of climate change, but not all will be able to effectively respond due to a lack of resources.[20] Climate change policy must therefore include all scales of governance to best respond to the challenges that lie ahead.

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[15] SCHLAGER, *supra* note 2, at 15.

[16] *Id.*

[17] *Id.*

[18] *Id.* at 18-19.

[19] SCHLAGER, *supra* note 2, at 20.

[20] *Id.* at 20-21.

SECTION 2: The Institutional Context

In Section 2, the book looks at federalism as a whole, its individual parts, and how federalism operates.[21] The challenge of federalism is combining its twin concepts of self-rule and shared-rule to benefit the interests of the individual, the nations, and the planet as a whole.[22] This section forms the legal and policy structure of the book by identifying forms of federalism, how American Indian tribes fit in the federal system and how governments, interest groups and citizens can best collaborate.[23]

Chapter 2: The Varieties of Federalism

The author of the second chapter, Robert A. Schapiro, explains the models of dual federalism and polyphonic federalism, ultimately arguing the latter is best suited for addressing climate change.[24] Dual federalism strictly separates federal power from state power so that there is no overlap and each level of government maintains its own designated area, nothing more and nothing less.[25] While the Great Depression seemed to lessen this categorical concept of federalism in the United States, the author thinks the Supreme Court today may be reintroducing dual federalism as reflected in its decision in *United States v. Morrison* and *United States v.*

[21] SCHLAGER, *supra* note 2, at 4.

[22] *Id.* at 31.

[23] *Id.* at 32-34.

[24] *Id.* at 35-36.

[25] SCHLAGER, *supra* note 2, at 37.

Lopez.[26] However, in his opinion, climate change cannot be divided so absolutely because its "problems and potential solutions are both global and intensely local, as noted in chapter I."[27]

Polyphonic federalism, unlike the dual concept, combines political authorities from state and federal levels and enhances their ability to act by facilitating "plurality, dialogue, and redundancy."[28] Plurality allows approaches to the same issue by both the state and the federal government so that the strengths and weakness of each can be identified and resolved to create better solutions.[29] Dialogue allows the dissemination of information from one area to another, so that jurisdictions can learn from one another and develop policy by learning from each other's wins and losses.[30] Redundancy, multiple actors addressing the same challenge, embraces the overlap of state and federal power and uses it to create stronger oversight which leads more resilient and innovative systems.[31] Polyphonic federalism is preferable to dual because, unlike dual federalism, the polyphonic approach "recognizes the need to develop intersecting global, national, and local responses to issues that cross jurisdictional boundaries" rather than trying to divide climate change into unworkable divisions between state and federal authorities.[32]

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[26] SCHLAGER, *supra* note 2, at 37-38.

[27] *Id.* at 38.

[28] *Id.* at 40.

[29] *Id.* at 40-41.

[30] SCHLAGER, *supra* note 2, at 42.

[31] *Id.* at 43.

[32] *Id.*

Chapter 3: Tribal Sovereignty and Climate Change: Moving Toward Intergovernmental Cooperation

American Indian tribes are another part of the federal framework and this chapter explains the role they play in regards to climate change. Underneath the often superficial assumptions of tribal relations with the US government there lays a deeper narrative of resource management.[33] The author explores the historical and legal framework of tribal sovereignty, then investigates the possible adaptation of tribal governments to climate-change policy and concludes by considering how the issues of resource depletion and nongovernmental organizations will contribute to tribal resource management in the future. The author describes historical federal Indian policy as five distinct eras, ending with the present era of self-determination.[34]

The book focuses on federal Environmental Protection Agency (EPA) laws and tribes as states, arguing that tribes should be seen as a "third sovereign" because of their inherent sovereignty and their statutory power from pollution control laws.[35] The National Environmental Policy Act in 1970 started US EPA tribal policy and continued in the 1980s when the EPA enacted a policy acknowledging tribal governments as "the primary parties for setting standards, making environmental policy decisions and making programs for reservations" and when Congress sanctioned treating tribes as states (TAS) in order to amend several EPA statutes such as the Clean Air Act, the Clean Water Act and the Safe Drinking Water Act.[36] In *Albuquerque v.*

[33] SCHLAGER, *supra* note 2, at 48-49.

[34] *Id.* at 51.

[35] *Id.* at 58-59.

[36] *Id.* at 59.

Browner, the Court upheld a tribe's right to set higher standards, like a state may do, and illustrated how a court can inquire into a statute's objective and intent to define a tribe's scope of power.[37] The impact of *Browner* is a "unique and vital extension of tribal sovereignty beyond the territorial limits of the reservation and where the regulation of a common resource" so that both tribes and states are empowered to "pursue higher standards and ensuring that neither party is precluded from seeking US EPA review."[38]

In the next section of the chapter, the author examines the role of environmental justice in terms of tribal sovereignty, climate change and international human rights. By accessing US Court and international bodies, tribes have been able to seek relief form climate-change on human rights grounds, demonstrating tribes' proactive approach to climate change policy.[39] The author concludes by emphasizing the importance of cooperation, echoing the arguments of the first two chapters. Like the specialized knowledge of localities and regions, the expertise contained in many tribal management organizations can and should be used to create effective climate change policy.[40]

Chapter 4: Collaborative Public Management and Climate Change

In this chapter, the author examines collaborative management and climate change. Collaborative public management builds off the idea of polyphonic federalism and advocates

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[37] SCHLAGER, *supra* note 2, at 59-60.

[38] *Id.* at 60.

[39] *Id.* at 48.

[40] *Id.* at 67.

multilevel approaches to climate change.[41] The author identifies the benefits and challenges of collaborative management and discusses the concerns that will determine the potential success of the system's climate-change policies.

Climate change policy poses a number of challenges because solutions are uncertain, there is no agreed upon best approach and no one jurisdiction or authority has the ability to solve global warming on its own.[42] Collaborative management is best addresses these challenges because "lacking one 'silver policy bullet,' a portfolio of policy strategies and instruments working on many different fronts and at different scales is needed."[43] Four types of collaborative management networks exist: informational; developmental; outreach; and action.[44] Implementing a collaborative federal-state climate change policy depends on context. A matrix is used to illustrate how ambiguity and conflict influence policy. Collaborative management makes the most of undesirable contexts. "In highly conflictual situations, collaboration supports conflict resolution, the building of social capital, and policy compliance. In situations of significant scientific uncertainty or ambiguous policies, collaboration supports learning and risk sharing."[45]

The biggest threat collaborative management faces is ensuring the cost of participation does not exceed the value of benefits received from contributing.[46] The author argues that laws regarding collaborative management must be clarified and incentivized so collaboration can be

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[41] SCHLAGER, *supra* note 2, at 73-74.

[42] *Id.* at 74.

[43] *Id.* at 75.

[44] *Id.* at 77.

[45] SCHLAGER, *supra* note 2, at 73.

[46] *Id.* at 86.

fully utilized.[47] Since collaborative management demands shared responsibility, accountability for performance becomes pivotal. The author believes internal and external transparency must exist among all actors and that performance metrics must be closely tracked and scrutinized.[48]

SECTION 3: Policy Initiatives Among and Across States

This section assesses individual state action and collective state interaction concerning climate change. Whether interaction occurs purposefully or accidentally, states end up learning from each other.[49] "It is by transforming how energy is generated and used that states are likely to have the greatest effect in mitigating climate change."[50]

Chapter 5: Policy Diffusion and Climate-Change Policy

Chapter 5 discusses how policy diffuses from state to state using political science research to evaluate the popularity of some policies and future implications. Competition, emulation and politics are the causes of diffusion.[51] The author takes a closer look political factors influencing climate change policy, such as agenda setting, information generation, customization and enactment.[52] With the aid of professional organizations, policy research institutes and think tanks, policy makers can gain a "clearer understanding of diffusion

[47] SCHLAGER, *supra* note 2, at 88.

[48] *Id.* at 88-89.

[49] *Id.* at 99.

[50] *Id.* at 102.

[51] SCHLAGER, *supra* note 2, at 102.

[52] *Id.* at 107.

mechanisms" in order to "better predict when diffusion is most likely to occur and when efforts to overcome the obstacles to diffusion should be directed."[53]

Chapter 6: Changing the Climate: The Role of Translocal Organizations of Government Actors (TOGAs) in American Federalism(s)

The role of nonprofit organizations, referred to as translocal organizations of governmental actors (TOGAs) in facilitating state collaboration is examined in this chapter. TOGAs form vertical and horizontal relationships, providing sources of law and policy that cut through and across the federal and state governments to create interjurisdictional bonds.[54] The US Conference of Mayors' Climate Protection Agreement is an example of a TOGA which realizes "'local,' 'federal' and 'international' interests are not fixed but emerge based on interactions among interdependent actors."[55] The US Senate has refused to accept the Kyoto Protocol, but 1,000 localities endorsed the agreement through the US Conference of Mayors.[56]

TOGAs' actions should not be seen as vertical or horizontal but diagonal, since they are uniquely both nongovernmental and nationally recognized..[57] TOGAs merit should have greater lawmaking powers because, through doctrine, statutes and regulatory rights, these groups would be responsive to the developments within US federalism that they represent.[58] Climate change

[53] SCHLAGER, *supra* note 2, at 103.

[54] *Id.*

[55] *Id.* at 125.

[56] *Id.* at 120.

[57] SCHLAGER, *supra* note 2, at 125-26.

[58] *Id.* at 132-37.

cannot be pigeonholed and TOGAS can create better policy and enhance understanding through actions that embrace the layers of federalism.

Chapter 7: Acting in Concert: State Efforts to Regionally Address Climate Change

Continuing the discussion of interaction between all scales of government, this chapter explores climate change administrative agreements, their strengths, weakness and obstacles. Administrative agreements embrace a polyphonic interpretation of federalism by enabling states to enact policies that address regional problems.[59] However, unlike compacts, states are not bound to follow such agreements so their effectiveness depends on cooperation.[60] Thus far, only administrative agreements have been used to pursue multi-state climate change goals and objectives.[61] The Northeast, West and Midwest states have engaged in administrative agreements more so than other US regions to form regional cap-and-trade systems and complementary policies involving energy production, energy efficiency and conservation and transportation.[62]

Ultimately, administrative agreements permit states to retain independence, foster collaboration around a particular region and can influence the national government.[63] Their flexibility both encourages their creation while limiting their effectiveness by allowing states to back out of nonbinding agreements.[64] Administrative agreements should be encouraged because "climate-change policy in a federal system is not an either/or proposition – for either state or the

[59] SCHLAGER, *supra* note 2, at 144.

[60] *Id.* at 144-45.

[61] *Id.* at 145.

[62] *Id.* at 149-51.

[63] SCHLAGER, *supra* note 2, at 159.

[64] *Id.*

federal government to enact. It is an 'and' issue – the states acting individually *and* collaboratively with each other *and* the federal government."[65]

Chapter 8: Reorienting State Climate-Change Policies to Induce Technological Change

In the final chapter of this section, the authors argue that state action can impact climate change because states are "well positioned to engage in technology development and adoption by creating incentives for businesses and consumers to adopt energy-efficient and alternative energy technologies."[66] States can design innovative policies that harmonize with federal regulations by looking at channels for technological change and gaps in the federal system.[67]

For the authors, technological change means the diffusion of existing technology rather than the creation of new technology, which is subject to speculation.[68] Several Scandinavian countries mixing environmental regulations and policies to incentivize technological change through a portfolio approach best addresses climate change.[69] The authors disagree with critics who argue that state policies cannot address global climate change by citing existing state programs centered on carbon emission caps, renewable portfolio standards, public benefit funds and tax credits, product standards and building codes.[70] States therefore play a meaningful role in the federalist response to climate change. While one state may not be capable of reducing global

[65] SCHLAGER, *supra* note 2, at 160.

[66] *Id.* at 101.

[67] *Id.* at 164.

[68] *Id.* at 165.

[69] SCHLAGER, *supra* note 2, at 168.

[70] *Id.* at 169-74.

greenhouse-gas emissions, it can impact climate change through programs that incentivize technological change, especially when integrated with federal programs.[71]

SECTION 4: State and Federal Dynamics

The final section of this book concentrates on the legal and policy interactions between the states and federal government to illustrate how this relationship can address climate change.

Chapter 9: Clean Air Act Federalism as a Template for Climate-Change Legislation

To demonstrate how national policy could be fashioned, the authors use the Clean Air Act as a model.[72] Focusing on reducing greenhouse-gas (GHG) emissions, the authors believe a cap-and-trade policy is politically acceptable, environmentally-effective and economical.[73] Illustrating the how the Clean Air Act works in the federal system, transferring that structure to GHG emissions would allow climate-change legislation to "set carbon emission reduction targets rather than asking the US EPA to set air quality standards for GHGs, but … leave to the states the primary role in determining how to meet those targets."[74] This again reflects the importance of a multi-scale approach to climate change. States are most capable of addressing their region's needs and the federal government is able to provide standards and supports.

Chapter 10: State Climate-Change Regulation: Will It Survive the Federal Challenge?

The chapter discusses how the American judicial system will determine the success of state action when federal legislation could preempt state climate-change policy. Even without

[71] SCHLAGER, *supra* note 2, at 176.

[72] *Id.*

[73] *Id.* at 176.

[74] *Id.* at 191.

federal preemption, courts still must "consider whether Congress left enough room for states to supplement federal climate-change legislation or foreclosed state regulation altogether."[75]

Presently, "legal doctrine interdicts certain kinds of state regulations but leaves the bulk of state regulation subject to judicial overview under vague standards of 'undue burden' or posing an 'obstacle' to federal law."[76] What seem like minor local changes can come together in the aggregate to greatly impact global climate change.[77] The authors promote a split solution: courts should reject regulations that discriminate against interstate, foreign commerce or other lawful transactions but should adopt a strong presumption of validity for state climate change regulation that can only be overcome if state law was in direct conflict with a statute or international agreement or clearly preempted.[78]

Chapter 11: American Federalism in Practice

The final chapter of this section examines how the inactivity of the federal government has allowed the states to take actions unique to their jurisdiction. Using past experiences, the author hypothesizes possible future policies and alternative approaches to climate change policy.[79] State policy concerning GHG emissions varies dramatically because of context, as illustrated by table 11.1 on state climate policies and greenhouse gas emissions intensity on page 236.[80] However, most states have chosen to take a less visible approach to climate change policy

[75] SCHLAGER, *supra* note 2, at 191.

[76] *Id.* at 229.

[77] *Id.* at 229

[78] *Id.* at 216.

[79] SCHLAGER, *supra* note 2, at 233.

[80] *Id.* at 236.

costs, paying more for a program that costs more as long as it is not a direct utility bill or at the point of product purchase.[81] The author outlines different options of state climate policy tools based on political feasibility and economic desirability, concluding that Cap-and-trade policies seem the most likely to be embraced, but the issue is still divisive.[82]

As states run up against the federal government, the future holds three possible directions for climate change policy: a shift toward top-down policy, continued bottom-up policy, or greater collaborative federalism.[83] Although the Obama administration and 111th Congress posed an opportunity for a new federal approach to climate change policy, the handful of climate change hearings and deeply divided Congress suggests that bottom-up policy development will continue.[84] Despite politics "that climate policy can no longer be framed as the exclusive province of international relations and instead must be acknowledged as an enduring challenge for multilevel governance."[85]

CONCLUSION: Celebrating and Protecting Diversity in Climate-Change Responses

In conclusion, the volume reiterates that in order to think globally, the multiple levels of American government must act locally. The authors argue that six principles should guide future policy: (1) local and regional actions create the foundation for climate-change response; (2) Congress and the executive branch should support state and local responses; (3) federal courts

[81] SCHLAGER, *supra* note 2, at 242.

[82] *Id.* at 248-49.

[83] *Id.*at 249-51.

[84] *Id.* at 252.

[85] SCHLAGER, *supra* note 2, at 253.

should narrowly construe preemption claims against state and tribal climate-change policy; (4) regional and non-governmental alignments should be supported; (5) Congress and state legislatures should encourage collaborative policy responses; and (6) federal policy must establish a national carbon pricing system.[86] Using the inherent strengths of the federal system, the United States can make a global impact on climate change through the collective power of its scales of governance.[87]

[86] SCHLAGER, *supra* note 2, at 258-61.

[87] *Id.* at 261.