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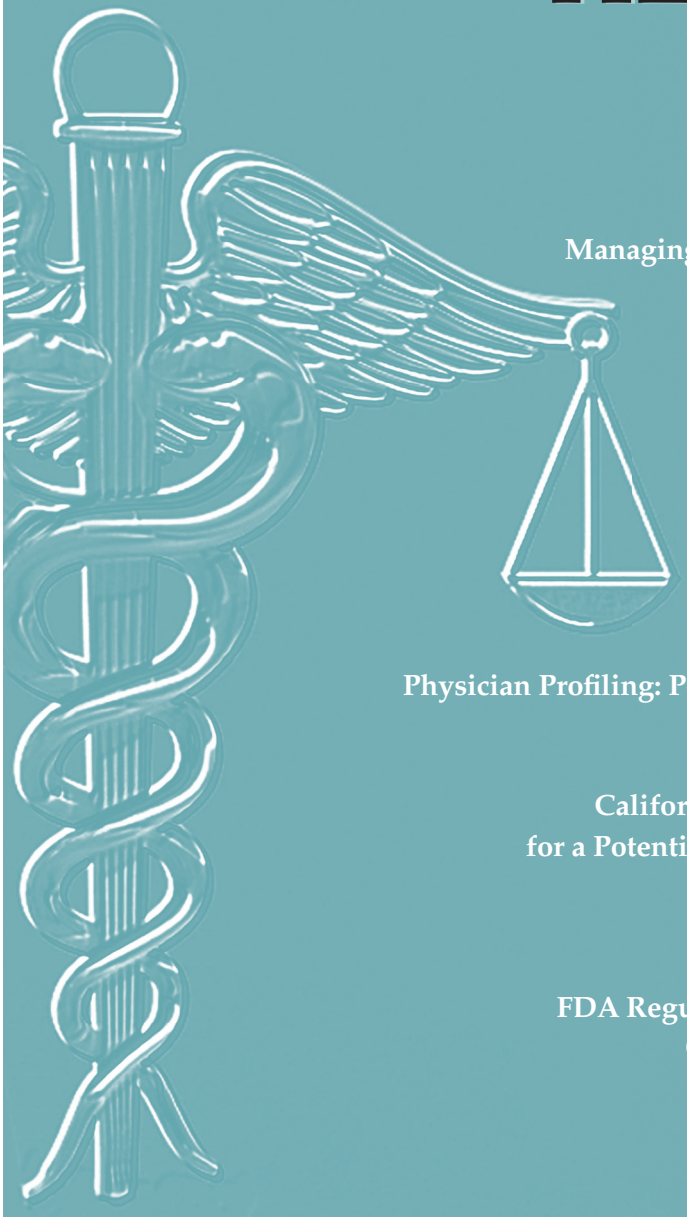

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Spring 2009 Staff

Health Law & Policy (HLP) is a publication of American University Washington College of Law (WCL) and the Health Law Project LL.M. Program on Law & Government.

Letter from the Editors

Dear *Health Law & Policy* Reader:

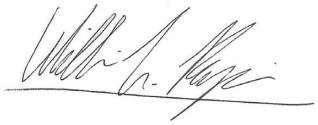
On behalf of the editorial board and staff, we proudly present this issue of *Health Law & Policy* (*HLP*). Now in our third year, we continue to strive to produce a publication that will both inform our readers of new and pertinent developments in the ever-changing field of health care, provide an opportunity for health law practitioners to contribute to scholarly discourse, and raise awareness for health issues in the greater legal community.

Our fifth issue opens with an article on ways to manage conflicts in health care innovation by one of the founding members of *HLP*. Following this article is model testimony by a Washington College of Law (WCL) pharmaceutical policy fellow that discusses data mining in the health care context. This issue also includes three articles that address the intersection of health and law and how to bring advancements to both. One of these articles analyzes the way in which we can use innovations from Deaf Culture to improve alternative dispute resolution. The student-written articles that follow explore flaws in health insurance law, and discuss the regulation of prescription drugs. Finally, our column section focuses heavily on the current economic climate and its impact on the field of health law.

This semester we co-hosted our second symposium at WCL on women's health care research, genetics, and sexuality. Transcripts of these presentations are forthcoming in the Fall 2009 issue of *HLP*. We are pleased to cover such a broad range of topics, and invite new authors to submit works for publication.

We extend our sincere gratitude and thanks to our advisor, Professor Corrine Parver, Esq., for her dedication and guidance. Further, we would like to thank our staff members for their efforts during the production of this issue. As we prepare to graduate, we are confident that *HLP* will continue its success under the leadership of the new executive board and staff. We hope that you enjoy this issue as much as we enjoyed putting it together.

Sincerely,



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Managing Conflicts of Interest in Health Care Innovation

*Georgiana Avramidis**

I. Introduction: Information Exchange Through Industry-Provider Interactions

Close and ongoing collaboration between health care professionals and the pharmaceutical drug, device, and biotechnology industries is a fundamental and necessary aspect of medical innovation. Companies interact with health care providers in a variety of ways: through product training sessions or conferences, sales and promotional meetings, consulting or investment arrangements, research and trial arrangements, economic remuneration, grants, or charitable donations.[1] Industry-provider interactions aim to promote public health through sharing and exchanging information between health care professionals, who have clinical experience and expertise and the health care industry, which has the resources to expend on innovative and critical treatments and technologies. These collaborations between industry and health care professionals save and improve the lives of millions of patients through medical breakthroughs and daily patient treatment.

The vital role of information exchange in advancing medical technology cannot be downplayed.[2] The clinical experience and expertise of health care professionals provides invaluable insight into industry research and development and initiates progress and innovation. In a recent example of the essential open flow of communication between clinicians and manufacturers, physicians relayed information to medical device companies about implanting metal plates into children's skulls.[3] The feedback from physicians prompted manufacturers to fashion smaller sized plates customized for children, thereby improving the quality of health care for a specific population.

Georgiana Avramidis is a 2008 graduate of American University Washington College of Law, and was one of the founding editors of Health Law & Policy. Ms. Avramidis joined Vertex Pharmaceuticals Incorporated in 2008.

Opponents of ongoing collaborations between industry and health care professionals express the belief that each health care player holds a conflicting and initially irreconcilable stake against the other's interests. Therefore, the mere appearance of such conflict draws suspicion of untoward behaviors and raises legitimate questions concerning the potential for prescriber bias. A close relationship between industry and health care professionals, however, does not necessarily indicate inappropriate relations or a relationship that will have a less beneficial effect on progress in health care. In fact, studies show that "fears that disclosed conflicts of interest are leading to tainted, unreliable recommendations are unfounded."[4] This does not necessarily mean that improper behavior does not arise out of interactions in which there are conflicts of interest.[5] The cases of *Moore v. Regents of California*[6] and *Gelsinger v. Trustees of Univ. of Pennsylvania*[7] drew a significant amount of public attention for the harm associated with research experiments in which physicians held a financial interest. In *Moore*, treating physicians influenced a patient's decision to undergo unnecessary tests, leading to an outcome that advanced their own gains rather than those of the patient.[8] The California Supreme Court held that by failing to disclose their personal interests in the treatment the physicians did not satisfy the duty to give informed consent, thereby denying the patient the opportunity to properly balance the risks and the benefits of continued treatment.[9]

Also in the realm of clinical research, the *Gelsinger* case associated the death of a teenage participant in a University of Pennsylvania research study with the principal investigator's conflicting financial interest in the outcome of the study, which prompted attempts to regulate or otherwise monitor physicians with an interest in research.[10] *Gelsinger* also presents a case where the industry-provider relationship was automatically viewed as unseemly because something went wrong.[11]

The information exchange works both ways. Health care professionals often rely on industry input and training to properly and effectively dispense pharmaceutical drugs and devices. While promoting the free exchange of information between health care players, this approach tends to be controversial when it involves seemingly extravagant gifts or payments for meals, travel, and consulting. Physicians con-

tend, however, that "the best approach to optimize cost effectiveness of product prescribing is to promote more, not less, interaction among all stakeholders involved in healthcare delivery."[12] Indeed, provided that the industry presents information to a physician without stipulation, the physician may decide freely which course of treatment to recommend.

The main purpose of industry-provider interactions is to promote an exchange of ideas and data regarding a product, an innovative idea, or a medical advancement.[13] In a conflict of interest analysis, where the conflict of interest is reviewed for its anticipated impact, the promotion of medical technology and innovation is generally the primary interest. For the information exchange to be worth the valuable time of health care professionals, however, ties with the industry often involve monetary or non-monetary incentives. For instance, secondary interests in the interaction may be the fee provided in exchange for a physician's consulting work. A secondary interest might also be a provider's interest in a company or the gain in reputation from association with a ground-breaking treatment or technology. Both primary and secondary interests are desirable. Although one may have "a claim to priority" that undermines the integrity of the first interest, in order to make the interaction beneficial for all parties involved the challenge is to ensure that both interests are realized.[14] Collaboration between these entities often gives rise to inherent conflicts of interest because incentives in industry-provider interactions are simultaneous and potentially incompatible.

II. Current Efforts in Managing Conflicts of Interest

In March and April of 2008, Congress responded to the growing mindfulness, if not wariness, of industry interaction with health care providers and its effects on the provision of health care by introducing legislation to regulate industry-provider interactions.[15] Known as the Physician Payments Sunshine Act, the legislation aims to "shed light" on collaborations in health care by mandating quarterly disclosure of interactions resulting in monetary amounts over a certain threshold.[16] By disclosing the existence of industry-provider interactions, the legislation empowers health care consumers with information about the development, the procurement, and the distribution of drugs and devices.

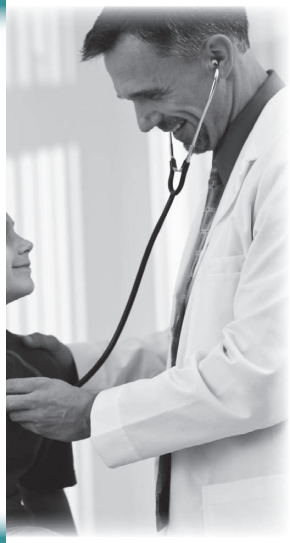
Disclosure legislation, such as the Physician Payments Sunshine Act and other state regulation, supplement efforts by industry trade associations to create institutional codes of ethics. Media coverage characterizes these efforts as aimed towards "reining in doctors," but the codes recognize the shared responsibility of the health care industry and providers in preserving public trust.[17] These approaches are voluntary and set the standard within each industry for the management of interactions with health care providers while promoting the best interests of the health care consumer. For instance, the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Health care Professionals provides guidance for interactions ranging from consulting arrangements to educational funding from pharmaceutical companies.[18] The Advanced Medical Technology Association's (AdvaMed) Code of Ethics on Interactions with Health Care Professionals provides guidance on the promotion of ethical industry-provider interactions in the device space.[19]

Legislative efforts, however, use disclosure as a means of regulating industry-provider interactions. While this is a reasonable and effective method of preventing abuse and negating the questionable impression that industry-provider ties often raise, it is important to recognize that conflicts of interest necessarily arise in all types of interactions where two or more intersecting interests exist. Moreover, in some cases, the outcome of an interaction that gives rise to an irresolvable conflict of interest is so desirable that it should nevertheless proceed. Where circumstances show that an interaction provides information so compelling and necessary, there is a rebuttable presumption that the interaction should continue despite a conflict of interest. This approach holds that industry influence negatively affects a physician's decision-making process and makes the assumption that by virtue of this potentiality, the dual interests cannot co-exist unless they pass the high "compelling circumstances" bar.[20] This approach is problematic because interactions that are useful in providing meaningful outcomes, but not necessarily "compelling" ones, are unable to proceed. Indeed, conflicts of interest are so ubiquitous that the benefits that arise from industry-provider interactions stall under the high bar set by the rebuttable presumption approach.

The interests of science and research are better served when existing conflicts are managed, instead of disallowed, because it is often the case that two intersecting interests can co-exist in a manner that allows both to be fulfilled. Under the management perspective, an advisory board may require an individual to recuse him or herself from involvement in a particular project, place any equity interest in a trust for the duration of the project, or encourage disclosure of conflicts

"Where circumstances show that an interaction provides information so compelling and necessary, there is a rebuttable presumption that the interaction should continue despite a conflict of interest."

of interest to manage the conflict. The last requirement, disclosure, simultaneously satisfies the health care professionals' desire to continue with a project, the regulating body's interest in limiting untoward behavior, and the health care consumer's need for information with which he or she can make knowledgeable decisions about treatment options. Disclosure that includes details providing context for each interest is necessary to determine whether the conflict of interest is manageable in a way that renders its outcome desirable despite any initial reservations.[21] This vital data aids health care consumers in understanding conflicts of interest in a way that does not preemptively find them unmanageable.



As the largest health care insurer in the nation and a major purchaser of pharmaceutical drugs, devices, and biotechnology, the U.S. government has a financial interest in overseeing any conflict of interest that arises between the health care industry and health care professionals to ensure that health care choices are made in the patients' best interest.[22] The government's attention to conflicts of interest in medicine is therefore aimed at controlling industry influence on prescribers' decision-making.

Interactions that promote innovation and information sharing, however, are in the best interest of the public. Any efforts to manage conflicts of interest through disclosure better serve health care consumers when tempered to encourage technological advancement. A thoughtful analysis of the value of managing conflicts of interest through disclosure includes an inquiry into the trade-offs of providing "light" on industry interactions. This article will suggest that disclosed information which is not properly managed through government or institutional regulation may hinder technological progress and information exchange between industry and health care providers. To ensure that the benefits of disclosure regulation outweigh its burdens, it is important to assess the information disclosed for its meaningfulness and for any unintended effects on the health care system. Finally, this article will suggest that disclosure of a conflict of interest is successful because it advances the fundamental value in health care of autonomy.

> "Through disclosure, industry has an opportunity to cast its pursuits as driven not only by profit, but by the pioneering of new and important technologies in medicine for the betterment of health care."

III. Value and Effects of Disclosures

Industry only gains when its products and technologies are implemented correctly and prescribed free of unseemly behavior. Technical procedures require that industry interact within health care professionals in operating rooms, private practices, and learning and training seminars without raising the specter of untoward influence.[23] Similarly, the financial support that health care professionals, and the health care system as a whole, acquire through industry is necessary to the promotion of research and development. This circular relationship establishes a conflict of interest.

A typical conflict of interest analysis calls for an inquiry into whether secondary interests can exist without jeopardizing the initial objectives of the industry-provider interaction. If the primary interest in an interaction between a pharmaceutical drug, device, or biotechnology company and a health care professional is collaboration towards an innovative medical product that promotes a better and more efficient health care system, then any secondary interests that directly interfere with that goal create a conflict of interest. A secondary interest may interfere either by compromising the original goal with tangible negative results (such as the *Gelsinger* case), or by affecting the mere appearance of impropriety. Generally, part of managing a conflict of interest includes acknowledging its existence through disclosures made to the public.[24] Industry benefits from full disclosure of its interactions with health care providers. Through disclosure, industry has an opportunity to cast its pursuits as driven not only by profit, but by the pioneering of new and important technologies in medicine for the betterment of health care. Moreover, industry has the opportunity to explain the important and justifiable reasons for its presence in a health care professional's practice. Disclosures detailing the circumstances of the industry-provider interactions help inform interested parties about the goals pursued by industry and the necessity for input from clinicians.

One of the benefits of disclosure legislation, which figuratively "shines light" on industry interactions, is the opportunity for industry to embrace disclosure as a means by which to shed the public perception of industry as a "dark force" and instead emerge as a vital means toward medical innovation and development. Industry's "bottom line" can, and does, co-exist with the promotion of public health.[25] Similarly, those goals can co-exist with the health care provider's interest in fees, investment, or other monetary or non-monetary gains.

Information exchanged through industry-provider interactions is so vital and so meaningful to advances in health care that discouraging collaboration based on the existence of a conflict of interest would ultimately cause more harm than good to the greater health care system.[26] Recently proposed guidance from the Food and Drug Administration (FDA) provided clarity on its prohibition of "unlawful promotion" of a product in the dissemination of off-label information in the form of medical or scientific reference publications and medical journal articles.[27] In its draft guidance, the FDA recognized the "public health value to health care professionals of receiving truthful and non-misleading scientific and medical information" and that such uses may in cases "constitute a medically recognized standard of care."[28] The Journal of the American Medical Association (JAMA) also recognizes the importance of impartiality and requires a neutral party to review industry-funded studies prior to publication. These efforts reflect recognition of the benefits arising from a health care professional in possession of clinical data that can improve a pharmaceutical drug or device, as well as assist a drug or device company by informing the company on how to best implement or use a product. In other words, the value placed on the exchange of information is often worth the risks that may arise from a conflict of interest. Disclosure of industry ties does not automatically negate the relationship. In more extreme instances, however, the specter of the disclosure itself is so detrimental that it threatens to negate those ties and the information attached to them.

IV. Unrestrained Disclosure May Harm, Rather than Promote, the Primary Interest of Improving Health Care by Obstructing the Information Shared

Although public disclosure of a conflict of interest in an industry-provider interaction is possible (or may be made possible through efforts of the parties involved), it is not necessarily information that *should* or *must be* shared if there are significant negative implications to its disclosure. Much of the regulation aimed at diminishing conflicts of interest actually regulates information exchange by setting standards for the types and the timing of disclosures. The level of required disclosure implicates the priorities that are placed on the information. To make informed value judgments an inquiry into the value of disclosures must incorporate questions around health care consumers' need to know certain information, how the information is made known, whether the need to know outweighs the potential for unintended consequence of harming progress, and ultimately, harming the health care consumer.

A. Disclosures that Unintentionally Tarnish the Medical Profession

A primary consequence for a company accused of maintaining untoward ties with physicians is diminished reputation in the public eye.[29] "Critics aver, and politicians echo that the most grievous casualty of conflict of interest—indeed of even the appearance of it—is the public "Trust."[30] Public trust in industry is not easily regained, although industry's indiscretions are more forgivable than those of a health care practitioner who has a longer way to fall based on a long-standing public perception as a trustworthy and upstanding professional.[31]

Although it has been suggested that pressure related to a managed care system has the effect of "un-aligning" the interests of the health care provider and consumer, physicians abide by the Hippocratic Oath, which bestows the responsibility to do no harm and act in the best interest of the patient.[32] This is not to suggest that industry-provider interactions go unchecked based on the assumed honesty of physicians, but rather highlights the sense of trust that embodies the profession.[33] As an illustration, physicians are held to a high legal standard of care that incorporates a sense of dependency on and regard for their knowledge and experience. Under the learned intermediary doctrine, for instance, physicians are charged with acting as the liaison between manufacturers and patients regarding the distribution and use of pharmaceutical products.[34] A recent case in Texas acknowledged that "[i]f the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided."[35] As a result of this public trust in the profession, attempts to regulate conflicts of interest in health care arose significantly later than efforts in other fields.[36]

As medicine becomes entangled in its function as a business, many questions that conflicts of interest raise relate directly to the seemingly contradictory role of the physician as a businessperson as well as a caretaker.[37] Indeed, it may be logical to suggest that collaboration in industry is another way that "doctors escaped becoming victims of capitalism and became small capitalists instead."[38] The role of a physician somehow entangled in capitalistic pursuits tends not to sit well with the public. As a result, alarm bells go off when we observe a physician motivated by the bottom-line or an otherwise unseemly objective such as reputation of investment.

Disclosure allows affected parties to view industry-provider interactions with "additional skepticism."[39] The first message that disclosure sends is that the health care provider holds an interest that conflicts with another goal in an industry-provider interaction. Insofar as the interests are managed or negated under the rebuttable presumption view, disclosure reveals that the physician has nothing to hide and as a result garners public trust through mere openness.[40] The second message that disclosure conveys, especially if it lacks specificity, is that industry ties may influence a physician's decision-making in a way that makes the care received untrustworthy.[41] Because disclosures incite suspicion of untoward behavior, they often lead to severe prophylactic measures to ensure that health care professionals behave in acceptable ways.[42] These extreme measures may unintentionally quell the exchange of information and the innovation that stems from this exchange.

The Massachusetts legislature recently passed a bill that seeks to ban industry gifts to doctors under the reasoning that the mere appearance of impropriety is enough to warrant a severe restriction of an industry-provider interaction.[43] The curtailing of industry-provider interactions fails to take into account the curbing of information sharing and exchange. As a result of the distrust attached to their interactions with industry, health care providers willingly reject fees and remuneration for their time spent consulting with pharmaceutical drug or device companies in order to avoid suspicion that may threaten their reputation.[44] For example, a recent *New York Times* article presented the stories of physicians who, after "intense scrutiny" for accepting compensation for consulting or speaking with pharmaceutical drug or device companies, now decline to accept any remuneration from

industry. One physician continued to provide services free of charge to a company based on his belief that the work performed for the company was vital to progress in medicine.[45] Another felt less incentive to participate in these important interactions without compensation for his time and efforts.[46]

B. Disclosures That Devalue the Information Exchanged

Insofar as a moral imperative to provide the best possible health care exists, it includes the duty to use the best possible information available. When a drug or device company possesses or learns of data with respect to its product, it bears a responsibility to share that information with health care consumers through physician intermediaries.[47] Likewise from the provider's perspective, possessing clinical data creates a duty to share that information with manufacturers who are in the best position to use it in a way that benefits patients. Thus, the fact that physicians must balance losing fees or losing trust is not the sole issue in sanctioning industry-provider interactions. The health care system also risks losing opportunities to share valuable information that promotes safe and effective innovation in medicine and leads to more informed prescribing and other decision-making.

> "The health care system also risks losing opportunities to share valuable information that promotes safe and effective innovation in medicine and leads to more informed prescribing and other decision-making."

Mistrust regarding the veracity and value of information born out of interactions where a conflict of interest exists is not exclusive to medicine, even though it has a particularly detrimental effect in the field. Even the specter of a conflict of interest raises questions about the integrity of the information provided. Moreover, information disclosed as part of an institutional policy or under government regulation actually reveals relatively little: it reveals only that the information may be suspect.[48] For these reasons, all disclosures regarding conflicting interests should be accompanied by a detailed summary of the circumstances of the interaction.[49]

Details in disclosure that qualify the physician's expertise and time spent are necessary to ensure that the data describes the interests of each party in a meaningful manner.[50] In this way, the circumstances under which gifts are received, consulting or speaking fees are paid, and other types of transfers are provided in context and tell a more complete story about the interests.[51] The time frame during which the holder of the interest invested in the company, the circumstances and reasons surrounding this investment, and even a pro-rated amount of the holding are all necessary to provide a more meaningful set of data with which one can make a more informed decision about the integrity of the information. As another example, payments made to health care providers for involvement in clinical research are often based on the intricacy or duration of the trial, providing a helpful context for payments that may otherwise seem exceedingly large or inappropriate. Further, the remuneration compensates for a physician's time spent away from his or her own practice, another detail that puts payment schemes into perspective. The key, therefore, is to ensure that the information provided is meaningful in the sense that it reveals the interest accurately. Providing context makes for a *truly full* disclosure and provides a complete set of data with which an affected party can more effectively analyze and manage the competing interests.

Despite proper disclosure, the Brennan study suggests an unconscious "impulse to reciprocate" for the donation of items and services renders interactions between industry and health care professionals by definition unmanageable.[52] Its basis in "soft sciences," however, has made the Brennan study vulnerable to skepticism, especially amongst physicians. The theory can even be viewed as insulting: few physicians are willing to risk their professional reputation, let alone the health of a patient, on the influence of a logo pad or pen.[53] More importantly, physicians generally rely on their training and experience in their prescribing and decision-making and are thus unlikely to be persuaded otherwise in the absence of true scientific data. Unlike conflicts of interest in other fields, a conflict of interest that arises in health care is not merely an inquiry into whether "reasonable onlookers would find it plausible that the *average person* could be swayed by a temptation."[54] Physicians are held to a higher standard both legally and ethically;[55] demoting their clinical judgment to that of the reasonable person seems in and of itself unreasonable.[56]

Information for the purposes of managing untoward interactions and disclosing conflicts of interests also has the unintended effect of revealing industry-provider interactions that lose their value when disclosed before a specific period of time. Device manufacturers in particular tend to be smaller start-up companies with little capital, but conduct research and development for intricate and sometimes unknown techniques or equipment. This type of innovation requires expert knowledge and clinical experience that at times only few possess: either the company's investors or specialists in a field. In addition, consulting or researching arrangements are sometimes made with physicians where the physician is so well known in

his or her community that disclosure of the interaction will "tip off" competitors as to developing goals of a company. Under the rebuttable presumption approach, this situation makes the case for proceeding with an industry-provider interaction despite a conflict of interest. More importantly, it suggests that certain disclosures may cause more harm than good when they automatically de-value the purposes of an interaction by negating a competitive edge.

V. Autonomy: The Overarching Interest

Arguably, "[i]nappropriate industry influence may be dangerous because it threatens to compromise physicians' judgment and prescribing patterns based on gifts or monetary incentives *about which patients are completely unaware*,"[57] highlighting the value of individual choice in the health care system.[58] When individuals are able to consider personally the implications that an interaction may have on treatment received or other health care choices, the principle of autonomy is maintained. Autonomy requires acquiring permission to perform medical procedures, providing ways to accommodate patient participation in treatment choices, and otherwise diminishing the chances that their person is abused.[59] These examples encompass a right that seems fundamental: the "right to know" as much information as is available. The value placed on the patients' "right to know" in the context of conflicts of interest mirrors its significance in health care issues that are similarly value-based, namely, informed consent and confidentiality of health care information.

That the U.S. health care system is a communal system with a strong emphasis on individual rights justifies a recent court decision finding that the free flow of ideas is fundamental to research and science.[60] The holding that the patients had given up ownership rights to tissue used in university research studies by granting consent demonstrates how respect for autonomy sufficiently mitigates the taking of individual information in pursuit of greater knowledge.[61] Indeed, the premium placed on providing informed consent is so high that any trade-offs associated with it, such as the physician's time spent supplying the requisite information, are generally viewed as "de minimus or not worth analyzing."[62] Providing for autonomous choice in health care decision-making protects research and choices in care that would otherwise be viewed as unusable or compromised. Likewise, without the disclosure of conflicts of interest, a patient's choice of treatment would not be truly informed and industry-provider interactions would not move forward in pursuit of improved health care.[63] Disclosure of pertinent information enables health care consumers to make more informed choices.[64] Thus, disclosure adequately manages conflicts of interest because it provides for patient autonomy in health care decision-making.

There are few cases of documented harm as a result of conflicts of interest arising out of industry-provider interactions. Instances where an individual is physically or financially harmed when confidentiality of health care records is breached are similarly negligible.[65] Even the recent breaches in confidentiality of "celebrity" health records at the University of Los Angeles, California Medical Center, where it would be foreseeable that a person in the public eye could indeed be injured by the leaking of health care information, left only the snooping employees harmed through loss of employment or other retribution. The outcome indicates that the breach itself was the offense, not the loss of privacy or release of information.[66] Nonetheless, we continue to "mark" health care records as confidential and to have strong negative reactions when that interest is breached.[67]

Likewise, protection against even the idea of unseemly behavior in industry-provider interactions is valuable in making informed choices, whether or not tangible "harm" is likely to occur. At the forefront of decisions regarding the uses and the disclosures of health care information is the sanctity of the individual's ability to make his or her own decisions about those uses and disclosures. The balance is therefore based on needs: the patient's need not to have his or her information disclosed takes priority over the need of an entity (other than a covered entity authorized under Health Insurance Portability and Accountability Act (HIPAA)) to use and disclose the information.[68] By protecting information about an individual's state of health, diagnosis, and treatment, it seems that what we are actually protecting is the long-regarded principle of autonomy.[69]

Health care records are confidential because they contain information that we have determined is the type of information that we must cover and conceal to the greatest extent possible. Similarly, we must balance whether the needs of industry or health care professionals to keep information undisclosed to prevent the unintended consequences described above trump the needs of health care consumers to know the information in those situations.[70] The trade-offs that occur when empowering health care consumers with information must be considered to the extent that they may harm the patient. Disclosures that lead to unintended consequences, such as physician recusal from interactions or other compromises that hinder innovation, should be better managed because the patient is at the receiving end of the information. In the end, the information that is disclosed contributes to the

"Providing for autonomous choice in health care decision-making protects research and choices in care that would otherwise be viewed as unusable or compromised."

patient's ability to make autonomous choices. As the beneficiaries of new medical technology, especially when providers are fully informed on its appropriate dissemination, the welfare of patients seems to be one objective that can trump the idea of fully informed autonomy.

VI. Conclusion

Jerome P. Kassirer, former editor of the New England Journal of Medicine (NEJM), acknowledges that "[a]t present, the national mood favors individualism, profits, and entrepreneurship."[71] The three major stakeholders in industry-provider interactions, industry, health care professionals, and health care consumers, all hold basic interests: financial return, medical innovation, and autonomy in health care. While seemingly incompatible, these interests intersect in more ways than they diverge when all stakeholders gain from the promotion of these simultaneous objectives.[72] When conflicts of interest threaten to deter a health care player from realizing its interest, disclosure of those interests maintains the "status quo."[73] The key to enabling each player to assess the risks and the benefits associated with moving forward is finding a balance between any competing interests and the disclosure thereof.[74] To the extent that unintended consequences are mitigated, disclosure simultaneously promotes patient autonomy while allowing medical innovation to move forward through designated interactions aimed at sharing and exchanging information about health care products and ideas.

1 For the purposes of this article, these will be referred to collectively as "industry-provider interactions."
2 *See* Ehud Arbit, Correspondence, *Academic-Industrial Relationships*, 353 New Eng. J. Med. 2720, 2720 (2005) ("Collaboration is the avenue to expediency and high quality from which we can all benefit.")
3 *See Doctors Call For Kid-Sized Medical Devices*, MSNBC.com, April 23, 2008, http://www.msnbc.com/id/24277116.
4 *See* Food and Drug Administration (FDA) Comment on "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings" (analyzing the data of a Public Citizen Health Research Group study concluding only a "weak relationship" between conflicts of interest and voting behavior of advisory board members and that the exclusion of members with conflicts would not change the vote outcome).
5 *See* Henry Beecher, *Ethics and Clinical Research*, 274 New Eng. J. Med. 1354 (1966) (presenting studies where providers made treatment choices that advanced their research interests and negatively affected the health of their patients).
6 51 Cal. 3d 120 (Cal. 1990), *cert*. denied 499 U.S. 936 (1991).
7 No. 001885, Pa. C.P., settled Nov. 2, 2000.
8 *See Moore*, 51 Cal. 3d at 126-27.
9 *See id.* at 131-32 (reasoning that informed consent includes the disclosure because an "interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment").
10 *See* Testimony of William F. Raub, Dep't of Health & Human Services, before the National Institutes for Health, Conference on Human Subject Protection and Financial Conflicts of Interest, Aug. 15–16, 2000, *available at* http://www.hhs.gov/ohrp/coi/8-15.htm (noting that the events of the *Gelsinger* case instigated the efforts of the conference, including new requirements and guidelines regarding clinical investigators and review of investigations).
11 *See* Tammy Meyer, *The Role of Company Representatives in the Operating Room – Are They Exposed to Liability?*, IADC Newsletter, October 2005, at 1 (relaying that "the plaintiff's attorney is sure to discover" the presence of a manufacturer representative in an operating room and may claim harm "'as a result of' this practice").
12 Harvard Docs: Bring on the Drug Reps, The Wall Street Journal Health Blog, http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog (April 17, 2008, 17:46 EST) (reporting on the comments made by Dr. Dennis Ausiello, chief of medicine at Massachusetts General Hospital and Dr. Thomas Stossel, Harvard Medical School in opposition to a proposed state ban of gifts to doctors from the pharmaceutical industry).
13 *See* Annetine C. Geljins & Samuel O. Their, *Medical Innovation and Institutional Interdependence*, 287 JAMA 72, 77 (2007) (describing the collaboration of health care scientists and industry as an "intellectual partnership" for working together to solve problems and promote new research).
14 *See* Dennis F. Thompson, *Understanding Conflicts of Interest* 329 New Eng. J. Med. 573, 573 (1993) (highlighting the "asymmetry between interests" in conflicts of interest in that "only one of the interests has a claim to priority, and the problem is to ensure that the other interests do not dominate").
15 *See, e.g.*, Barnaby J. Feder, *New Focus of Inquiry Into Bribes: Doctors*, N.Y. Times, March 22, 2008; Barry Meier, *Implant Program for Heart Device Was a Sales Spur*, N.Y. Times, Sept. 27, 2005; Reed Abelson, *Possible Conflicts for Doctors Are Seen on Medical Devices*, N.Y. Times, Sept. 22, 2005; *U.S. Picking Up Pace of Device Inquiries: Probe to Focus on Allegations of Fraud, Abuse*, Boston Globe, May 19, 2004. In addition to media attention, recent cases such as Gelsinger have brought considerable attention to the issue. *See supra* note 7.
16 *See* Physician Payments Sunshine Act of 2008, H.R.5605, S.2029, reintroduced in 2009, *available at* http://aging.senate.gov/letters/ppsabill2009.pdf.
17 *See* Arlene Weintraub & Amy Barrett, *Medicine in Conflict*, BusinessWeek, Oct. 23, 2006, at 77.
18 Pharmaceutical Research and Manufactures of America (PhRMA), Code on Interactions with Health Care Professionals (effective 2009), http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf.
19 Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals (Sept. 2003), http://advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf.

20 Association of an American Medical Colleges (AAMC) Task Force on Financial Conflicts of Interest in Clinical Research: *Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research 7* (2001) (providing as an example of a compelling circumstance the situation in human subjects research where an individual is so "uniquely qualified" that the research cannot be conducted safely and effectiveness without his or her involvement).

21 *But see* Daylian M. Cain et al., *Coming Clean but Playing Dirtier: The Shortcomings of Disclosures as a Solution to Conflicts of Interest*, *in* Conflicts of Interest: Challenges and Solutions in Business, Law, Medicine and Public Policy 108 (Don A. Moore et al., eds. 2005) (providing for the respective benefits to stakeholders, but proposing that disclosure's effect may be "overestimated" because the information may not be meaningful to those it is intended to affect).

22 *See* Bernadette M. Broccolo & Jennifer S. Geetter, *'Health' and 'Life Sciences': The Inevitable Merger of Distinct Industry Sectors*, 1 BNA's Life Sciences Law & Industry 2 (2007) (accounting for increased government interest in regulating the relationships forged between those life science companies and health care providers, as related to the changed role of government from a health care payor to an active health care purchaser).

23 *See* David A Shaywitz & Dennis A. Ausiello, *Scientific Research With an Asterisk*, Boston Globe, April 29, 2008 (extolling on the importance of industry-provider interactions in providing new treatments).

24 *See, e.g.* Robert S. Schwartz, et al., Editorial, *Full Disclosure and the Funding of Biomedical Research*, 358 JAMA 1850, 1850 (2008) (emphasizing that disclosure reporting is necessary in biomedical research because "one cannot fully appreciate a study's meaning without acknowledging the subtle biases and interpretation that may arise when a sponsor stands to gain from the report").

25 *Cf.* Robert M. Tenery, Jr., *Interactions Between Physicians and the Health Care Technology Industry*, 283 JAMA 391, 393 (2000) (asserting the idea that industry goals compete with the best interests of health care consumers).

26 *See infra* Section II.

27 *See* Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publication on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, Feb. 2008, *available at* http://www.fda.gov/oc/op/goodreprint.html.

28 *Id*.

29 *See, e.g.*, Statement by David Dvorak, Zimmer Holdings President and Chief Executive Officer, Zimmer Announces New Compliance Model (Apr. 17, 2008) (announcing the company's steps to change its methods of interacting with physicians to regain public trust after questions regarding its interactions with orthopedic surgeons arose through alleged anti-kickback violations, but maintaining that "[c]ollaboration with physicians will always be critical to advancing medical technology that improves patients' lives").

30 Thomas P. Stossel, Regulating Financial Conflicts of Interest in Medicine: A Solution in Search of a Problem, Presentation before the Hofstra University Conference on Biomedical Ethics and the Law (Oct. 4–5, 2006), *in* Medical Progress Today, Oct. 10, 2006, at Slide 2.

31 *See* Harris Poll, Doctors and Teachers Most Trusted Among 22 Occupations and Professions: Fewer Adults Trust the President to Tell the Truth, August 8, 2006, *available at* http://www.harrisinteractive.com/harris_poll/index.asp?PID=688 (ranking doctors as the most trusted profession with 85 percent of adults polled indicated they trust doctors to tell the truth).

32 *See* Kevin W. Williams, *Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting*, 59 Food & Drug L.J. 45, 46 (2004) (asserting that the parallel pursuits of the physician and the patient have now been altered under the managed care setting that provides incentives for physicians based on the utilization and reporting of services).

33 *See* Jerome P. Kassirer, *Coming Clean but Playing Dirtier: The Shortcomings of Disclosures as a Solution to Conflicts of Interest, in* Conflicts of Interest: Challenges and Solutions in Business, Law, Medicine and Public Policy 139 (Don A. Moore et al., eds. 2005) ("Unless medicine is willing to give up its long legacy of public trust that avers that doctors are performing in their patients' best interests, the culture of ready acceptance of the industry's largesse must change.")

34 *See* Paul Starr, Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry 26 (New York: Basic Books 1982) (highlighting the significant role of the "gatekeeping authority" because it gives physicians the "purchasing power" where "the authority to prescribe is the power to destroy").

35 Ackermann v. Wyeth, No. 06-41774, slip op. (5th Cir. Apr. 24, 2008), at 6.

36 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific 'Conflict of Interest,' in* Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability, 63, 63-64 (Trudo Lemmens and Duff R. Waring, eds., 2006).

37 *See* Paul Starr, Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry 424 (New York: Basic Books 1982) (foreseeing the practice of medicine a "zero-sum game" where competition drives physicians to make choices that may not benefit the patient population).

38 *See id.* at 25-27 (describing physician collaboration with, rather than against, insurance companies, hospitals, and other "bureaucratic organizations" that allows them to maintain their income and professional autonomy).

39 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific 'Conflict of Interest,' in* Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability 63, 69 (Trudo Lemmens and Duff R. Waring, eds., 2006).

40 *See* Dennis F. Thompson, *Understanding Conflicts of Interest* 329 New Eng. J. Med. 573, 573 (1993) (noting that the regulation of conflicts of interest upholds the integrity of and confidence in the profession).

41 *See* Sheldon Krimsky, *The Ethical and Legal Foundations of Scientific 'Conflict of Interest,' in* Law and Ethics in Biomedical Research: Regulation, Conflict of Interest, and Liability 63, 69 (Trudo Lemmens and Duff R. Waring, eds., 2006) (describing the effects of a conflict of interest revealed only after harm has occurred, thereby lessening public trust).

42 *See* Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships – Solving Problems or Stifling Progress?*, 353 New Eng. J. Med. 1060, 1063 (2005).

43 *See* Harvard Docs: Bring on the Drug Reps, The Wall Street Journal Health Blog, http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog (April 17, 2008, 17:46 EST) (reporting on the strong opposition taken by physicians who call the proposal "'severe and vague, [and] inviting . . . personal grievances to harass physicians . . . [and] inevitably inhibit[ing] appropriate industry support'").

44 *See* Gina Kolata, *Citing Ethics, Some Doctors Are Rejecting Industry Pay*, N.Y. Times, April 15, 2008.

45 *See id.*

46 *See id.*

47 In the case of the medical device industry, manufacturers and providers often forge vital relationships in order to provide effective and efficient training for devices that would be useless or harmful in the hands of an untrained professional. *See* Paul A. LaViolette, *Medical Devices and Conflict of Interest: Unique Issues and An Industry Code to Address Them*, 74 Cleveland Clinic J. Med. S26 (2007) (pointing to the interactive nature of devices as making "critical" physician interactions with medical device companies and calling for the implementation of the AdvaMed Code of Ethics to manage those interactions).

48 There is also an argument that "[i]f everyone is disclosing, it's as if no one is disclosing." In other words, the value of the information being disclosed becomes a "mere formality." *See* Arlene Weintraub & Amy Barrett, *Medicine in Conflict*, BusinessWeek, October 23, 2006, at 78 (quoting Dr. Ezekiel J. Emanuel, chair of the Department of Clinical Bioethics at the National Institutes of Health).

49 The Association of an American Medical Colleges and the Association of American Universities (AAMC-AAU) Advisory Committee suggestion that "[d]isclosure [of conflicts of interest] should be extended both in scope and in audience" does not go far enough in providing the vital context need to portray the conflict of interest as it truly exists. Its recommendation is limited to disclosure of the type of interaction between industry and the health care provider, but not specifics such as length or timing of remuneration or duration of the interaction. *See Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research, February 2008, at 10.

50 *See* Testimony of Christopher L. White, Executive Vice President, General Counsel and Secretary, The Advanced Medical Technology Association (AdvaMed), before the Senate Special Committee on Aging, Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry, February 27, 2008, http://aging.senate.gov/events/hr188cw.pdf (suggesting that disclosure legislation include the opportunity for information providing context of an industry-provider interaction because "[i]f sunshine is going to work, then patients need to understand what they are looking at and what it means"). Mr. White goes on to say that failing to provide context for an interaction could have the negative effect of discouraging physicians from collaborating with industry, which "would be a disservice to patients who are looking for the next breakthrough in medical technology that could improve their lives." *See id.*

51 As part of its recent deferred prosecution agreement, Zimmer must list its interactions with physician consultants on its website. *See supra*, note 28. The information required, however, includes only the name, city of residence, amount and type of payment. *See* Deferred Prosecution Agreement, Zimmer website, para. 41, http://www.zimmer.com/web/enUS/pdf/Zimmer_DPA.pdf. No other contextual information that would create a more complete image of the interaction is required. *See* Company Consultants – Identification and Payments, Zimmer website, http://zimmer.com/web/enUS/pdf/Company_Consultants5. pdf.

52 *See* Troyen A. Brennan, et al., *Health Industry Practices That Create Conflicts of Interest*, 295 JAMA 429 (arguing that disclosure is ineffective in mediating the influence of gifts, meals, lectures and conferences, and samples because even the smallest influence is an absolute manipulation of decision-making).

53 *See, e.g.*, Harvard Docs: Bring on the Drug Reps, Comments, The Wall Street Journal Health Blog, http://blogs.wsj.com/health/2008/04/17/bring-on-the-drug-reps/?mod=WSJBlog (April 17, 2008, 17:46 EST) (postings of Keith Hartman MD in Wisconsin stating: "Frankly, I buy my own pens, but have learned a great deal from pharm-industry seminars and even some of the drug reps . . ." and Industry Must fight back!! stating: " . . . to say a pen or two from a pharma company influences how a doctor treats his/her patients is as ludicrous as it is demeaning and uninformed").

54 Howard Brody, Correspondence, *Academic-Industrial Relationships*, 353 New Eng. J. Med. 2720, 2720 (2005) (emphasis added).

55 *See infra* Section IVa.

56 Moreover, "what reasonable onlookers find plausible on the basis of appearances is opinion, not fact." Thomas P. Stossel, *Correspondence, Academic-Industrial Relationships*, 353 New Eng. J. Med. 2720, 2720 (2005) (responding to the points raised by Dr. Howard Brody, *see supra* note 54).

57 Robert M. Tenery, *Interactions Between Physicians and the Health Care Technology Industry*, 283 JAMA 390, 392 (2000) (emphasis added).

58 *See* Beaufort B. Longest, Jr., Health Policymaking in the United States 52-53 (AUPHA 1998) (explaining that respect for autonomy, which includes truthful information sharing, pervades health policymaking).

59 *See* Cobbs v. Grant, 8 Cal.3d 229, 243 (Cal. 1972) (holding that the physician has a duty of "reasonable disclosure" of available treatment choices to the patient).

60 *See* Washington University v. Catalona, 437 F.Supp. 2d 985 (E.D.Mo. 2006), *cert. denied* January 22, 2008.

61 *But see* Lori Andrews, *Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona*, 34 J. L., Med. & Ethics 398, 405 (2006) (forewarning a chilling effect on research when patient control over the use of donated information is not enforced).

62 *See* Peter Schuck, *Rethinking Informed Consent*, 103 Yale L.J. 899, 939 (1994) (reflecting that "courts tend to invoke the values of autonomy and decision-making and then analyze the implication of those values, while maintaining a silence on the issue of costs.")

63 *See* Cobbs v. Grant, 8 Cal.3d 229, 240 (Cal. 1972) (quoting Prosser on Torts (4th ed. 1971) that consent is necessary to meet the professional standard of care).

64 "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." Canterbury v. Spence, 464 F.2d 772, 780 (D.C. 1972).

65 *See Health Privacy Stories*, Health Privacy Project, March 5, 2007 (canvassing the "harms" befalling individuals subject to a breach of health care records. Very few of the harms include physical or proprietary assaults).

66 *See* UCLA Hospital Employee Couldn't Contain Celeb Curiosity, The Wall Street Journal Health Blog, http://blogs.wsj.com/health/2008/04/07/ucla-hospital-employee-couldnt-contain-celeb-curiosity/?mod=WSJBlog (April 7, 2008, 9:25 EST).

67 *See* Thomas Claburn, *Government Report Finds Health Care Privacy Breaches Rampant*, InformationWeek, September 5, 2006 (reporting that almost half of health insurance contractors and Medicaid agencies experienced a privacy breach in health care records, a statistic that Beth Givens, the director of Privacy Rights Clearinghouse finds "shocking" both because of the large number and the nature of the data).

68 *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA).

69 *See* Beaufort B. Longest, Jr., Health Policymaking in the United States 52 (AUPHA 1998) (relating that the principle of autonomy as envisioned by the founders of the United States arises in health care in privacy rulemaking).

70 *See supra*, section IV.

71 Jerome P. Kassirer, *Coming Clean but Playing Dirtier: The Shortcomings of Disclosures as a Solution to Conflicts of Interest, in* Conflicts of Interest: Challenges and Solutions in Business, Law, Medicine and Public Policy 139 (Don A. Moore et al., eds. 2005).

72 *See* David A Shaywitz & Dennis A. Ausiello, *Scientific Research With an Asterisk*, Boston Globe, April 29, 2008 (presenting the view of two physicians that the "battle is not drug companies v. academics, but rather between dreadful diseases and the medical researchers who are trying to subdue them").

73 *See* Cain, *supra* note 21 and accompanying text.

74 *See* Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454, 464 (2003) (suggesting that conflicts of interest are here to stay and a "consensus around a system of checks and balances to promote medical innovation while improving oversight and transparency" is necessary).

Testimony: The State Role in the Regulation of Prescription Data-Mining

*Meredith Jacob**

I. Overview

This model testimony is based off of specific testimony Meredith Jacob has submitted to various state legislatures advocating the passage of "Data-Mining" legislation.

Dear Chairman and Members of the Committee:

I am pleased to submit these comments on the practice of prescriber profiling and the sale of physician-specific prescription data. My comments provide an overview of the practice of prescription data-mining, a review of legislation passed in other states to regulate it, and an analysis of the recent decision of the United State Court of Appeals for the First Circuit upholding the New Hampshire data-mining restriction.

My name is Meredith Jacob and I am a pharmaceutical policy fellow at the Program on Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law. I am here on behalf of the Prescription Project of Community Catalyst, as well as the National Legislative Association on Prescription Drug Prices. PIJIP's associate director, Sean Flynn, serves as counsel to the Prescription Project of Community Catalyst and to the National Legislative Association on Prescription Drug Prices. These organizations strongly support the passage of legislation to regulate "data-mining" by the pharmaceutical industry.

II. The Use and Abuse of Prescription Data-Mining

The practice of prescription data-mining dates back to the early 1990s, when prescription records went digital and pharmacy benefit managers (PBMs) became widespread. These organizations sought to digitize prescription records so claims could be expedited through an online process, creating the possibility of quickly transferring the records to others. Over the last decade or so, a multi-billion dollar "health information" industry has emerged to buy prescription records from pharmacies, PBMs and other intermediaries to compile massive databases on the prescribing habits of nearly every physician and other licensed prescriber in the country.

The records are then used by pharmaceutical companies to promote incredibly sophisticated marketing efforts to doctors. Pharmaceutical companies use the records to determine which doctors are more susceptible to various kinds of sales messages, which doctors are more prone to using new drugs, whether a doctor is "brand loyal" to a certain manufacturer, and which doctors should be rewarded for their prescribing practices with high paying consultancies, advisory board positions, and scholarships to "educational" seminars. Data-mining has radically increased the influence of marketers by allowing them to specifically observe and reward the most profitable prescribing practices while tailoring switching messages to those not using desired products.[1]

Access to prescribing data stoked a massive increase in spending and sales force size for individualized marketing. According to the First Circuit's examination of the record in the New Hampshire case, pharmaceutical companies spend at least $4 billion annually on detailing to doctors.

In the decade after IMS Health Inc., a large Health Information Organization, unveiled its flagship prescriber tracking program in 1993,[2] spending on detailing increased by nearly 300 percent,[3] doubling the number of pharmaceutical sales representatives to over 100,000.[4] There is now one pharmaceutical sales representative for every four to five office-based physicians in the nation. Because low prescribers often do not receive sales attention, it has been estimated that the effective ratio of sales representatives to targeted doctors is closer to one for every 2.5 doctors. The average primary care physician in 2004 interacted with a staggering 28 sales representatives each week.[5]

States are now acting to regulate this use of prescription data for several core reasons:

- First, prescriptions are part of medical records that document private decisions made in the context of the doctor patient relationship. Permitting commercial use of these records improperly injects marketing influence into the exam room.

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- Second, there is a large amount of data displaying that drug marketers in the United States are exerting undue influence over the prescribing practices, which is contributing to irrational prescribing practices that harm public health and unnecessarily raise the cost of health care.
- Third, access to this data is corrupting the medical profession by allowing companies to use advisory board appointments, consultancies and gifts as direct payment for observed prescribing practices.
- Finally, doctors themselves are pushing for this legislation in many states because access to individualized data is promoting the use of harassing and vexatious sales practices in which sales representatives attempt to hold doctors "accountable" for gifts and promises as they race toward the massive bonuses companies provide to reps based on their ability to shift prescribing practices.

All of these purposes provide ample justification for state regulation in this area, regardless of any "free speech" arguments raised by the industry.

III. State Regulation of Data-Mining: First Circuit Upholds the New Hampshire Prescription Privacy Act

New Hampshire, in passing its Prescription Confidentiality Act,[6] was the first state in the nation to ban the trade in prescriber-identified prescription data for marketing purposes. Following the passage of the New Hampshire Act, Vermont[7] and Maine[8] passed laws that give physicians the right to opt-in or opt-out of sharing their prescription records.

The first-in-the-nation prescription confidentiality law in New Hampshire was recently upheld under a constitutional challenge by the First Circuit Court of Appeals. All three judges on the First Circuit agreed that the law's core purpose of curbing irrational prescribing of higher priced drugs due to undue influence of marketers was sufficient in itself to justify any encroachment on the companies' "commercial speech" rights. Two judges held that the law did not actually regulate any speech because prescription records sold as a commodity on commercial markets are subject to traditional economic regulation free of any First Amendment inquiry. The third judge thought that the law did affect the commercial speech of detailers, by prohibiting them from informing their messages with the records, but held nevertheless that the law was adequately justified.[9]

The first area of inquiry for the First Circuit was whether the use of prescriber-identifiable data should be classified as speech. Here, the court found that the use of data prohibited by the New Hampshire Act constituted conduct, not speech. The Court reviewed other cases where language-related activities were regulated as conduct, rather than speech, and found that in the case at hand there was "scant societal value" to any informational component of the marketing uses of prescription data.

The Court noted that, in this situation, information had become a commodity, and could be regulated as such. The sale of prescription data did nothing to increase the free flow of information to doctors or patients, or to inform their decision-making in the marketplace. Finally, the Court reviewed precedent establishing that state actions that made speech unprofitable did not restrict speech, and observed that no provision of the New Hampshire Act foreclosed publication or open discussion of prescriber data.

IV. Creating a Full Record

Although the only circuit court to address the issue unanimously held that states have every right to ban the sale of prescription records to serve public health concerns, the litigation in these cases indicates that legislatures must carefully justify their actions to survive court scrutiny. If anything, the risks of litigation for the next state to act in this area have increased. The pharmaceutical industry is now looking for a circuit split so it can take this issue to the Supreme Court.

The most important thing this Committee can do—other than carefully crafting legislation—is to create a full and persuasive record displaying the reasons for its action in this area. While data-mining legislation should not be subject to First Amendment scrutiny, the Committee should assume that a court may differ on this opinion and that the law will have to meet what courts term "intermediate scrutiny." This means that the law must directly serve a "substantial government interest" and be reasonably tailored to that interest. There is a wealth of documentary evidence and expert testimony that can be brought to bear on these issues.

Regulation of Data-Mining Prevents Undue Influence in Pharmaceutical Marketing

States have a paramount interest in combating undue influence of pharmaceutical marketers over prescribing decisions. Nearly all direct-to-prescriber marketing is one-sided because only the most expensive and profitable medicines, that is branded blockbuster

> "Access to prescribing data aggravates the negative impact of this one-sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior."

drugs, are marketed through in-person detailing.[10] Access to prescribing data aggravates the negative impact of this one-sided information market by permitting branded medicine marketers to observe and reward favored prescribing behavior.[11] The most favored prescribers can receive hundreds of thousands of dollars in payments from drug companies for speaking engagements, research, and sitting on various advisory boards.[12]

Numerous studies and investigations have documented a significant, measurable, and increasing influence of direct-to-physician marketing by convincing doctors to adopt prescribing practices that are contrary to clinical guidelines and the weight of objective scientific evidence.[13] An exhaustive data synthesis from over 500 published studies has found conclusive evidence that pharmaceutical detailing guided by access to prescribing data "impact[s] the prescribing practices of residents and physicians in terms of prescribing cost, non-rational prescribing, awareness, preference and rapid prescribing of new drugs, and decreased prescribing of generic drugs." [14] The same study concluded that meetings with pharmaceutical representatives had a direct relationship to physician requests to add drugs to a formulary that had "little or no therapeutic advantage over existing formulary drugs."[15]

Data-Mining Fueled Marketing Increases Cost Without Benefit to Patients

The aggregate financial costs to society of undue influence by pharmaceutical marketers are enormous. Many examples exist exhibiting the successes of the super-charged pharmaceutical marketing system at shifting massive amounts of prescriptions toward newer, more expensive drugs that do not benefit patients. In 2007, while generic medicines accounted for 65% of prescriptions filled, generics were only responsible for approximately 20% of prescription costs.[16] Reducing the non-medically appropriate overuse of branded pharmaceuticals is essential to controlling health care costs. Another study found that approximately 40% of Pennsylvania Medicare patients on antihypertensive therapy were being prescribed medications at odds with clinical guidelines, at a cost of $11.6 million per year in that state alone. Extrapolated to national levels, that same study found that marketing-driven non-rational prescribing costs the nation $1.2 billion for that class of drugs alone. [17]

Increased Prescription Costs Reduce Access to Medicines or Force Patients to Cut Spending on Other Necessities

Increased cost of medications has a direct effect on patient health. In 2007, a review of medical literature found that up to 32% of seniors took less medicine than prescribed in an effort to reduce costs.[18] When data-mining drives the prescription of more expensive alternatives, patients are needlessly forced to make purchasing decisions that can endanger their health.

Data-Mining Accelerates Unsupported, Overly-Broad Adoption of the Newest Drugs

One of the clear effects of data-mining in marketing is that it demonstrably shifts prescribing patterns toward newer drugs. But now there is a growing awareness that the rapid uptake of new drugs may threaten patient health in many areas where older therapies should remain the first line drugs of choice.[19] Newer drugs often have unknown side effects and less developed safety profiles, in comparison to drugs that have been on the market for significant periods of time.

This effect can be seen in the incredible marketing push and resultant prescription surge for Vioxx, Celebrex, and other COX 2 inhibitors, despite the lack of any conclusive medical evidence that they were more effective than older pain medications, or that the reduction in gastric side effects were significant for most patients. In the case of Vioxx, aggressive marketing using prescriber data helped facilitate the widespread adoption of a drug that was far more dangerous to patient health than existing alternatives or than the company's marketing messages admitted.

Regulation of Data-Mining Maintains Standards in the Medical Profession

Many physician organizations advocate an end to prescriber-identified data trading for marketing purposes because the practice threatens the ethical standards of the profession and jeopardizes physicians' relations with patients by permitting pharmaceutical companies to give pecuniary rewards to medical professionals based on their prescribing habits.

Gift bans and reporting are one good policy tool. But it is difficult and perhaps impossible to ban all payments to doctors by pharmaceutical companies, because some legitimate roles exist for physicians in clinical trials and other consulting roles. By banning sale of prescriber data, we can eliminate payments to physicians based on the drugs they prescribe, rather than work they do.

"Reducing the non-medically appropriate overuse of branded pharmaceuticals is essential to controlling health care costs."

> By banning sale of prescriber data, we can eliminate payments to physicians based on the drugs they prescribe, rather than work they do.

Regulation of Data-Mining Protects Doctors Against Vexatious Sales Practices

Doctors are pushing many of the reforms in this area in part because a substantial number feel harassed by the increasing frequency and aggressiveness of detailing forces fueled by the use of prescribing data to track prescription writing and calculate sales bonuses.[20] A host of federal and state laws combat harassing and frequent marketing calls on consumers by limiting marketers' access to identifying information. In the case of medicines, it is the doctors who make the purchasing decisions for the ultimate consumers of the product; therefore, they receive the large majority of all marketing efforts.

In addition to being harassing by its sheer volume, access to prescriber histories increases the prevalence of coercive marketing practices in individual sales calls. Sales representatives use this data in increasingly obnoxious ways to hold prescribers "accountable" for their marketing messages and gifts, including by telling prescribers that they are being monitored and that the free lunches and gifts will dwindle if they do not meet the marketers' expectations.[21]

Regulation of Data-Mining Protects Patient Privacy

Patients have the strongest possible interest in not having their treatment histories subjected to surveillance and lobbying by pharmaceutical companies. But this interest cannot be protected by the removal of patients' names alone. Patient de-identification is not complete with the removal of names and addresses. The data can still be used to track an individual patient, identified with a unique numerical identifier that carries forward through time.[22] With access to prescriber identities and "anonymized" patient data, a pharmaceutical company can observe a specific treatment event for a particular patient, like the switching of a prescription, and respond with an individualized marketing campaign at the prescriber to change that treatment. This insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an invasion of privacy of the most odious kind: one that directly affects the treatment course of the patient for the pecuniary interest of another through a breach of confidentiality that is nearly impossible to detect.

Thank you for this opportunity to testify.

1 *See*, Carl Elliott, The Drug Pushers, Atlantic Monthly, April 2006, 90; Liz Kowalczyk, *Drug Companies' Secret Reports Outrage Doctors*, Boston Globe, May 25, 2003, at A1.

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3 Kaiser Family Foundation, Trends and Indicators in the Changing Health Care Marketplace exhibit 1.20, http://www.kff.org/insurance/7031/print sec1.cfm (2005).

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Technology Mediated Dispute Resolution and the Deaf Community*

*David Allen Larson** and Paula Gajewski Mickelson****

The work of American Sign Language (ASL)/English interpreters is filled with complex interpersonal, linguistic, and cultural challenges. "Interpreting is a discourse process in which interpreters are active participants who need to . . . understand interactional behavior as well as explicit ways in which languages and cultures use language . . . interpreters make intentional, informed choices from a range of possibilities."[1] The decisions and ethical dilemmas interpreters face on a daily basis are countless and the potential for disagreement regarding those decisions is great. Technology Mediated Dispute Resolution (TMDR)[2] processes can be particularly helpful when misunderstandings and conflicts arise. Conversely, the communication skills that the Deaf Community and interpreters employ routinely can provide valuable insights for everyone who uses new technologies to communicate and resolve disputes.

When a consumer or colleague believes a working interpreter has violated the underlying principles and guidelines set forth in the 2005 NAD-RID Code of Professional Conduct (CPC),[3] he or she may file a grievance at the Registry of Interpreters for the Deaf (RID), a national professional organization for sign language interpreters and transliterators. The RID, established in 1964 and incorporated in 1972, has experienced a short history of vigorous growth and development. The formative first eight years included publication of the first Code of Ethics for sign language interpreters. The Code is not revised often; the most recent revision was approved and released in July, 2005. The 2005 NAD-RID CPC is now the document professional interpreters, transliterators, and students of interpretation look to for guidance.

The RID maintains a triad of programming which includes the Ethical Practices System (EPS), the National Testing System, and the Certification Maintenance System. These complementary programs support and enforce the quality of service and ethical behavior expected from professional Sign Language interpreters. They include both the CPC and a mediation system to address grievances filed against interpreters. If mediation fails to resolve the conflict in a manner that satisfies both the complainant and the working interpreter (the respondent), then the complaint is referred to a formal adjudication process.[4] Mediation, however, has become the core process of the EPS.

David Allen Larson previously addressed the opportunities and dangers inherent in technology.

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Larson believes that Alternative Dispute Resolution (ADR) practitioners and theorists must study the way in which individuals increasingly use technology to communicate. Those practitioners and theorists then must determine how those technologies can be integrated into dispute resolution processes most productively. He offers three distinct reasons why we need to approach technology in this manner: (1) teens and preteens rely heavily on technology to communicate and we need to become competent in those technologies; (2) fuel prices continue to rise and technology allows us to communicate effectively without incurring travel expenses; and (3) security concerns have made physical travel less convenient and perhaps less safe.[5]

This article examines the mediation process within the RID EPS and suggests when and how technology may be utilized to enhance that process. Background information regarding the interpreting profession, the Deaf Community, and the process for filing and reviewing grievances will provide a context for this discussion. An overview of the technologies already being used within the Deaf Community and the interpreting field will help to determine where new technologies can be introduced most effectively. Each of the three steps in the EPS will be analyzed to assess how additional technologies can be integrated productively. Finally, peripheral activities surrounding the EPS and mediation process will be identified, highlighting elements in which technology may be used.

I. The Interpreting Profession

At its most basic level, interpreting is the process of facilitating communication between two or more parties who do not share a common language. The work of ASL/English interpreters incorporates spoken English and ASL or, in recognition of the linguistic diversity within the American Deaf Community, a variety of signed English and ASL. Researchers in the field further define interpreting by addressing the complex relational, linguistic, and cultural elements inherent in an interpreter's work and decision making processes.[6] For instance, Dennis Cokely defined interpretation as:

> The competent and coherent use of one naturally evolved language to express the meanings and intentions conveyed in another naturally evolved language for the purpose of negotiating an opportunity for a successful communicative interaction in real time within a triad involving two principal individuals or groups who are incapable of using, or who prefer not to use, the language of the other individual or group.[7]

In Cokely's article, "interpreter" is defined as a professional possessing cultural competence and linguistic fluency who facilitates communication between Deaf and non-Deaf individuals in a variety of settings. Inherent in this definition are the complexities illustrated in Cokely's previously noted definition. The generic term Deaf is used to represent consumers of interpreting services in the United States who use Sign Language to communicate. The term includes not only members of the American Deaf Community who use ASL, but also individuals who use a variation of signed English.

Many people mistakenly assume that ASL is simply English on the hands. Nothing could be further from the truth, as is pointed out by Baker-Shenk & Cokely (1980) in their timeless text for teachers of ASL and Deaf Culture entitled *American Sign Language: A Teacher's Resource Text on Grammar and Culture*:

> The vocabulary and syntax of English have developed within a community of users who can speak and hear. ASL, however, is a visual-gestural language with its own vocabulary and syntax. The vocabulary and syntax of ASL have developed within a community of users who rely upon their bodies and eyes. The differences between these two languages in the areas of vocabulary and syntax are significant.[8]

Interpreters work in a variety of settings including, but not limited to, legal, medical, employment, social service, and educational. The decisions interpreters make in each of these environments can make an indelible impression on the lives of those involved. The depth of this impact is keenly assessed by Cokely:

> As individuals, and certainly as interpreters/transliterators, we face choices that can have profound effects on other people and their lives—choices of how we will act in certain situations. The choices we make, and the actions that follow from those choices, can uphold or deny the dignity of other people, can advocate or violate the rights of other people, and can affirm or disavow the humanity of other people.[9]

To say the work of interpreters is complex and therefore ripe for conflict could be described as a gross understatement. Nonetheless, interpreted exchanges occur successfully a great majority of the time. There are times, however, when consumers or interpreting colleagues believe a working interpreter has made an unethical decision warranting attention by the Ethical Practices System (EPS) of the RID. When that situation occurs, the objecting party can file a formal grievance.

"To say the work of interpreters is complex and therefore ripe for conflict could be described as a gross understatement. Nonetheless, interpreted exchanges occur successfully a great majority of the time."

The RID, the national professional organization of interpreters in the United States, understands that conflicts can escalate into an experience that is both unfortunate and harmful for all parties involved. The EPS Policy and Procedures Manual points out that the RID encourages parties to make every effort to resolve the conflict on their own. The parties should attempt to clarify the dispute with one another and refer to the CPC and RID staff for further assistance.[10] RID also acknowledges that for a variety of reasons some disputes may not be independently resolved and that individuals may choose to file a formal grievance.[11] The Manual is written in a first-person narrative directly to the complainant and thoroughly describes the process for filing a grievance.

A complaint, as defined in the Manual, must: (1) be based on the possible violation of the official NAD-RID CPC; (2) be filed due to an incident related to the provision of interpreting services; (3) describe an incident that occurred after the interpreter's services were contracted through a verbal or written agreement, either on a paid or volunteer basis; and (4) be filed as a result of the contracted interpreter's conduct prior to, during, or after an interpreting assignment.[12]

The complaint may be submitted in written English, or videotaped and submitted in ASL, and must be received by the RID within 90 days of the alleged violation.[13] Once the complaint has been received, intake begins (the first of the grievance procedure's three processes: intake, mediation, and adjudication). During the intake process, the complaint is reviewed by RID national office staff and is either accepted because it meets all of the conditions required of a complaint as defined above, or it is rejected because it does not satisfy one or more of the same criteria.

Mediation is relatively new to RID. Mediation is a problem-solving process in which a neutral third party engages the disputing parties in a conversation, helps them define the problem, identify their interests and work towards resolution. Mediators, unlike arbitrators and judges, do not issue an award or render a judgment. Mediation became an integral part of the grievance process in 1999 as a result of motions that were passed by the membership and Board of Directors.[14] The minutes from the 1999 convention reveal two reasons why the membership included mediation in the grievance process: (1) the desire that grievances be processed in a timely manner; and (2) the belief that ADR was the most cost-effective approach.[15] Although these reasons typically are relevant whenever one considers any ADR process, TMDR processes are particularly well suited to address these concerns.[16]

Since 1999, nearly 160 complaints have been filed against interpreter practioners, with over 30 ending with mediated agreements.[17] The mediators are members of the National Association of the Deaf (NAD) and/or the RID and are "interpreters and Deaf individuals who have completed professional mediation training through RID. All of the mediators are fluent in ASL and knowledgeable in Deafness and the interpreting process."[18] RID generally sends a team of mediators (frequently a Deaf person and an interpreter) to each session and chooses the team based on their availability and their geographic location.[19] In an effort to increase the comfort levels and respect the privacy of the complainant and respondent, RID tries to send mediators from outside of the geographic region where the mediation will take place.[20]

If a resolution is reached, then a mediation agreement is written by the mediator, signed by both parties and filed with RID.[21] The RID EPS coordinator or designee monitors the terms of the agreement.[22] Once the terms are satisfied, the case is closed.[23] If an agreement is not reached, then a non-agreement form is signed by both parties and the original complaint is referred to the next step in the grievance process, adjudication.[24]

A panel of three peer adjudicators evaluates the evidence of the alleged violation and determines whether the action was in violation of the NAD-RID Code of Professional Conduct.[25] If a violation is found, then the panel determines the necessary sanctions (in contrast to a mediator).[26]

Relying upon the preceding description of the interpreting profession, the Deaf Community, and the grievance filing process this article will now explore how technology can be further integrated into the RID Ethical Practices System. Section II will analyze how technology is being used in TMDR systems and then suggest how those technologies can be combined with the technological advances already adopted in the Deaf Community and interpreting profession.

II. Technology

Technology has not been embraced by alternative dispute resolution practitioners. Regardless of whether dispute resolvers are intimidated by technology, are creatures of habit, or simply are convinced that traditional face-to-face approaches are more productive, neutrals are not recognizing technology's potential. There are certain populations and circumstances, however, which are uniquely prepared for TMDR. The Deaf Community, for example, has demonstrated that technology facilitated communication can be very effective. Deaf people are well-positioned both to increase reliance on technology in their own dispute resolution systems and to teach other communities how technology can improve communication and dispute resolution.

A. Technology and ADR

TMDR includes and expands upon the potential for problem solving offered by online dispute resolution (ODR). Parties communicating online can send e-mail, meet in secure online virtual spaces, chat using instant messaging, exchange messages on listserves, stream video, or videoconference. ODR systems can facilitate negotiation or mediation or they can offer virtual juries and different arbitral processes.[27] Some commentators still use the term ODR even when online communication is used in combination with more traditional offline forms of technology based communication such as fax, telephone, and standard mail.[28] Other terms have been used in the literature to represent technology facilitated communication, such as computer mediated communication (CMC) and information and communication technologies (ICT).[29] Technology Mediated communication (TMC) is a term describing communication facilitated by technology. If one relies on TMC to resolve a dispute, then he or she is engaged in Technology Mediated Dispute Resolution (TMDR), a term that embraces the full range of technology-based communication options as opposed to focusing solely on online communications.[30] For purposes of this paper, the focus on a holistic view of the technology reflected in TMC and TMDR will be used when considering the application of technology to the RID EPS.

> The fact that technology allows parties to preserve communications, review them on demand, and perhaps correct or further explain those communications can be invaluable where two parties are communicating in different languages.

Technology can improve dispute resolution processes. It does not take much imagination to recognize that technology can save parties both money and time. Additionally, certain individuals may be more comfortable relying on technology mediated communications rather than face-to-face exchanges. The fact that technology allows parties to preserve communications, review them on demand, and perhaps correct or further explain those communications can be invaluable where two parties are communicating in different languages. When an interpreter, a Deaf person, and a mediator (or a team of mediators) are working together the parties are likely to communicate in ASL. It is likely that ASL is not the native or natural language of one or more of the parties. As a result, it might prove very helpful if their communication can be reviewed repeatedly or supplemented.[31]

There are, of course, challenges. When parties do not have equivalent experience, access, or skills concerning technology every effort must be made to minimize or eliminate those disparities. When dispute resolution system designers begin relying on video all parties will need an infrastructure sufficient to support that technology. The specific technologies employed must be accessible to each individual.

When the Deaf Community does not participate in the design of a technology based communication system, that system may not be accessible. The accessibility concern is shared by individuals with a wide variety of disabilities. The danger is so real that on December 21, 2007, the U.S. House of Representatives responded by releasing a draft of the "Twenty First Century Communications and Video Accessibility Act."[32] This draft addresses, among other issues, hearing aid compatibility, relay services, internet-based services and equipment, universal service support, closed captioning decoding (expanding requirements from televisions with screens thirteen inches or larger to all video devices that can receive or display simultaneously transmitted video and sound), video description capabilities, digital television technology compatibility, and conspicuous first level on-screen menu access for closed captioning and video description user interfaces.[33]

Technology can protect parties from uncomfortable or threatening face-to-face confrontations and offer vulnerable individuals a place where their communications can appear as forceful as the statements of someone who is physically much larger and louder. That said, technology is not a panacea and parties still can be victimized.

Cyberbullying is a fact of life in Cyberspace. For example, approximately one-third (32%) of the 935 teenagers surveyed by the Pew Internet and American Life project report that they have been the targets of behaviors ranging from annoying to potentially menacing.[34] The unwelcome conduct includes sending threatening messages, forwarding e-mail and text messages without consent, posting pictures without permission, and spreading rumors online.[35] Yet there is evidence that virtual spaces provide more protection from bullying than one finds in the physical world. Two-thirds (67%) of the surveyed teens agree that bullying and harassment occur more often offline than online and less than one-third (29%) report that this unwelcome conduct occurs more frequently online.[36] Despite the relative safety that virtual environments offer, cyberbullying is a very real concern and a danger about which individuals must remain vigilant.

Parties sometimes believe that when they engage in technology-based communications, as opposed to face-to-face communications, they cannot create the trust that may be required to resolve a dispute. While the specific strategies and techniques employed by neutrals to establish trust may have to be adjusted when working in a virtual environment, principles and concepts basic to any dispute resolution process still provide guidance.

Katsh and Rifkin assert that there are three fundamental features that must be considered when developing an ODR or TMDR system: convenience, trust, and expertise.[37] A convenient process must be accessible both financially and physically and the process must be user-friendly. Katsh and Rifkin recommend that, "the convenience level must be set at the lowest common denominator."[38]

The parties must at some minimal level trust each other, the technology, and the third-party neutral(s). The importance of trust in this environment cannot be overstated: "while a lack of convenience creates a feeling of frustration, lack of trust results in a feeling of risk."[39]

Finally, a TMDR/ODR system must offer expertise. A system that provides expertise does not simply produce useful information. That system also will provide a valuable process; a process that keeps the parties engaged and moving towards a resolution.[40] Collecting and sharing information will not be sufficient. The parties must believe that the technology adds value beyond what they could accomplish on their own.

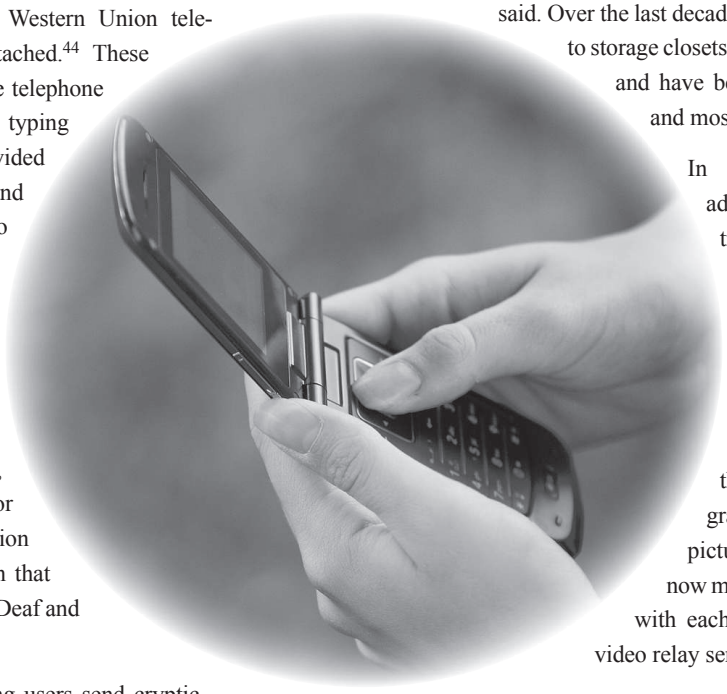
Katsh and Rifkin provide a graphic illustration of this concept in the form of a convenience, trust, and expertise triangle.[41] The emphasis placed on each of these three features, and thus the shape of the triangle, will vary depending upon the parties involved and the circumstances. If a problem is particularly troubling,

for example, then the parties may be willing to participate even though the process is not particularly convenient. In this situation, the shape of the triangle changes and becomes elongated. The convenience feature is represented by the short side of the triangle and the trust and expertise features appear as longer sides.[42] The respective weights that are assigned each feature require careful consideration.

B. Technology and the Deaf Community

Technology is not new to the Deaf Community. Deaf people have a long history of creatively adapting technology to help them live in a non-Deaf world. For instance, they use various visual signaling devices to alert them to crying babies, doorbells, and phones ringing. They used caption decoders before laws mandated that texting technology be included in televisions. Deaf persons have long used various technologies to communicate when face-to-face meetings were not possible.[43]

The first Teletypewriters (TTYs), also known as Telecommunication Devices for the Deaf (TDDs), were Western Union teletypewriters with a phone coupler attached.[44] These devices allowed Deaf people to use the telephone and call others with similar machines, typing messages to one another.[45] TTYs provided significant independence for Deaf and hard of hearing individuals who no longer needed to rely on others to make telephone calls on their behalf. Despite the benefits of TTYs, there also were drawbacks. Typed conversations took much longer to complete than spoken communications. As a result, Deaf people incurred higher phone bills, particularly when they made numerous or lengthy long-distance calls.[46] This situation eventually was remedied by legislation that provided discounts on phone service to Deaf and hard of hearing people.[47]



When cell phone and instant messaging users send cryptic text messages to each other it might appear that nuance, tonal cues, and emotional cues are sacrificed in exchange for speed and efficiency.[48] Yet if we look to the Deaf Community, we can see that cues are communicated and that emotions, even subtleties, are not an inevitable casualty of a text-based communication system. Long before a colon, a dash, and a half parentheses conveyed a positive mood with a smiley face :-), the Deaf Community was communicating emotion—ha ha (laughter), ILY (I love you), OXOX (hugs and kisses) and SMILE (conveys you are smiling)—and using "cryptic messages" as a strategy for making the TTY conversation more efficient—CUL (see you later), msg (message), mtg (meeting) and NP (no problem).[49]

As a result of widespread adoption of e-mail, instant messaging, and text-messaging (short message service known as SMS[50]), technology users throughout society are learning how to communicate emotion in a text-based environment. Individuals can use text-markers that underscore or **emphasize** *important* ideas.[51] Additionally, sensory words can create images and a feeling of physical presence, for instance, when one states "I feel," "I sense," or "you've got me scratching my head."[52] One should not use sensory words indiscriminately and must be careful regarding assumptions when communicating in a text-based environment. Braeutigan's examples include "I see" and "so, what I am hearing." Message recipients who are not able to see or persons who do not hear may not appreciate references to senses they do not possess. If one makes sensory allusions within a question rather than a statement, for example, and asks repeatedly "Do you hear me?," then that characterization may interfere with the effort to build trust and rapport.

When the Americans with Disabilities Act (ADA) was enacted in 1990, the Telecommunications section required that telecommunications relay services be provided for people who are Deaf or hard of hearing.[53] Telephone relay services (TRS) employed hundreds of operators across the country, connecting Deaf and hearing callers by reading what the Deaf caller typed on their TTY and typing back to the Deaf caller what the hearing person said. Over the last decade, however, TTYs have been moved to storage closets as a back-up communication device and have been replaced by pagers, Sidekicks, and most recently, videophones.

In the mid-1990s, technological advances offered a new twist on the traditional relay service-video relay. Deaf people used videophones and the internet via high-speed services to connect with a communication assistant (a qualified interpreter) who dialed the non-Deaf caller on a traditional phone and interpreted the call.[54] The initial technology was grainy and did not offer a very clear picture, but that has since changed and now many Deaf people are communicating with each other via videophones and using video relay services (VRS) on a daily basis.

The impact of this technology on the Deaf Community cannot be understated. In the spring of 2007, the National Association of the Deaf (NAD) and others hosted a demonstration of Video Relay Service in the U.S. Senate and House of Representatives.[55] The NAD President, Bobbie Beth Scoggins, declared "[b]eing able to communicate in American Sign Language when making telephone calls levels the playing field for Deaf consumers. Interested persons attending the event will see how VRS works firsthand and gain a greater understanding and appreciation of its far-reaching value to the American Deaf community."[56] Scoggins' comments are noteworthy in that they underscore an inherent advantage realized in VRS services and videophones: Deaf people can communicate in their natural language, American Sign Language. Although TTYs, Sidekicks and other text-based technologies were appreciated and utilized, those English language based devices required Deaf users to communicate in literally a second language. Consequently, users confronted the same challenges faced by other second language speakers and the risk of misunderstandings and misinterpretations increased.

> In fact, in light of the opportunities that technology offers, Deaf children may be even more engaged with technology than their peers who are not Deaf.

The exponential increase in the use of videophones and VRS[57] is only one example of how technology has impacted the Deaf Community. The Community also is finding an ASL-friendly medium in YouTube[58] and V-logs.[59] While YouTube contains postings from both Deaf and non-Deaf people about a wide range of topics, V-logs increasingly are being used to conduct rich discussions about significant ASL and Deaf Culture issues in ASL. V-logs are a form of blogs.[60] Although V-logs, or video logs, can be used for a multitude of purposes, Deaf individuals use V-logs to post ASL messages they have recorded.

Although there is much talk in the Community about the affordability of, and access to, high-speed internet options for Deaf and hard of hearing people, the equipment is readily available. Many VRS providers offer Deaf consumers free videophones and education on how to use the technology and VRS services.[61] The services are free of charge to the end users because the Federal Communications Commission (FCC) administers the program that supports VRS and reimburses providers on a per-minute basis for calls processed.[62]

Larson describes Millennials as "digital natives in a land of digital immigrants."[63] Deaf children are certainly no different. In fact, in light of the opportunities that technology offers, Deaf children may be even more engaged with technology than their peers who are not Deaf. Deaf children who are growing up in homes with videophones and Sidekicks and posting V-logs on the Internet may not worry whether there are TTYs stored safely in the hall closet, "just in case."

C. Technology and the Interpreting Profession

The profound impact that technology and VRS have had on the Deaf Community also is felt by the interpreting profession. Many interpreters, particularly those who interpret in their own private practice on a freelance basis, have utilized various technologies both to stay connected with their clients and to run their businesses more efficiently. Technology's impact on the interpreting profession can be observed, for example, in the June 2007 issue of the *VIEWS*, the monthly newsletter published by the Registry of Interpreters for the Deaf. The entire issue is devoted to technology, distance communications, and video interpreting. RID President Angela Jones' article outlines the different ways RID has embraced technology, which includes forming Yahoo! groups[64] for activities of various committees and task forces, videophone usage by all RID board members, the unveiling of a new and improved RID website,[65] and the implementation of a policy regarding the use of traditional e-mail as well as the use of video e-mail.[66] Jones embraces the message of John S. Parke, President and CEO of Leadership Synergies, LLC, who declares: "As technology continues to dominate our society, it is vital for organizations—particularly nonprofits—to stay ahead of the game. Board members of nonprofits should recognize how some of the latest technology could spur their organizations to new heights."[67]

In the same issue, Weisenberg and Garcia offer words of caution with regard to VRS and its impact. They suggest that a history similar to that seen in the industrial revolution may be repeating itself with the advent of VRS, routinizing and depersonalizing the work of interpreters.[68] Recognizing that one must be attentive to the short- and long-term implications of VRS for the Deaf Community and interpreting, the RID leadership nonetheless is modeling ways in which technology can be used productively.

III. Technology and the RID Ethical Practices System

As illustrated above, Deaf Community members consciously, creatively, and routinely have adopted various technologies in order to live in a non-Deaf world. Many interpreters and neutrals, however, have not been as proactive. Although some interpreters and neutrals have embraced technology with a passion, it is not difficult to sympathize with those who have not adopted the most recent technologies. In light of the pace at which technology is advancing, it sometimes seems impossible to stay informed. Nonetheless, it is important to consider the ways in which technology can improve dispute resolution processes for everyone involved—parties, neutrals, and interpreters. When considering which forms of TMC could be used most effectively in the RID EPS, one must focus on both the people and the context.[69]

The parties most likely to be involved with disputes processed by the EPS are Deaf people, non-Deaf consumers, and interpreters. Deaf people, interpreters, and neutrals involved in EPS mediations typically have used some form of technology-assisted communication in the past. Regardless of one's initial comfort level with technology, the RID is encouraging the use of technology. Accordingly, it makes sense to explore how technology mediated communications can be integrated into the current EPS system.

Individuals participating in the EPS may have dramatically different levels of experience and comfort when it comes to technology. Consequently, a variety of technologies must be available that lend themselves

to different combinations. EPS coordinators and/or the mediators first must assess a party's abilities concerning technology. Although the simplest solution is to employ the technologies that represent the lowest common denominator, one should not assume that the parties will be unable or unwilling to be educated regarding more sophisticated technologies.

The Deaf Community is not populated by technophobes. The challenge, in fact, may be to educate the interpreters, neutrals, and the non-Deaf participants. Because Deaf people will be involved in nearly every dispute resolution process, either as complainants, respondents and/or mediators, videoconferencing and video-based technology appear to be most compatible with the visual–gestural nature of ASL. Additionally, given the popularity of video-based technology in the Deaf Community in V-logs, videophones and VRS, it is likely that many Deaf people will have some level of familiarity and experience with this technology.

Most video-based technology supports a synchronous process, allowing disputing parties to communicate in real-time with each other and the mediators. Asynchronous TMDR does have certain advantages, however, which the RID EPS and participants should not ignore. An asynchronous communication system provides opportunities for careful review before a participant transmits a hurried message, lets heated and unproductive emotions cool, allows for research and consultation before each communication, and creates flexibility and convenience when it comes to scheduling and participation.

There are disadvantages to an asynchronous system. For example, anyone who has sent an e-mail message and, while waiting for a reply, felt his or her emotions drift from eager to puzzled to anxious to irked to angry can appreciate one of the difficulties associated with asynchronous communication. When one party does not reply promptly and does not provide an explanation for the delay, a conversation that was developing productively can instead deteriorate rapidly.

A dispute resolution process designer should invest the time necessary to identify specifically the advantages and disadvantages of each TMC option. The process available for each dispute does not need to be identical. Nonetheless, in light of the Deaf Community's familiarity with technology, disputing parties usually should be given synchronous, video-based communication options as well as the opportunity for asynchronous communication. Videophones, for example, can be incorporated into the Ethical Practices System.

Videophones have specific system requirements that must be satisfied in order for the technology to function properly. Each VRS service provider makes recommendations regarding the specific requirements needed to support their service. All the service providers are governed by the FCC.[70] The FCC requires videophones to be compatible across systems.

According to CSDVRS,[71] computers must have: Pentium III–800 MHz or higher processor, 8MB video card (16 MB video card is recommended), 16K color (minimum), 256 MB RAM, 20 MB free disk space, USB based web cam, cable, DSL, or other broadband Internet connection.[72] The minimum Digital Subscriber Line (DSL) or cable speed needed to support VRS are 256 Kbps upload and download speed; 256kbps upload and download speeds or higher are recommended for optimal use and clarity.[73]

The web cameras CSD VRS recommends include the Logitech Quickcam for Notebook Pro or the Logitech Quickcam Pro 4000 or 5000.[74] The camera must have a CCD sensor—CMOS sensors are not recommended because they may slow down the videoconference capabilities.[75] Sorenson VRS manufactures the Sorenson VP 100, Sorenson VP 200, and the i2eye D-link videophones that they exclusively distribute.[76] The Active X and Net Meeting software also are required to support VRS calls and may be downloaded via a link available on the CSD VRS website.[77]

Other videoconferencing technology may be an option when considering TMDR and RID. For example, the College of St. Catherine in St. Paul, Minnesota uses a Tandberg 3000 MXP Video Conferencing System, which provides excellent quality video transmission for ASL users to communicate from distant locations.[78] The connection is made via Internet2, which provides greater capacity and much faster connectivity than the regular Internet.[79] The system supports direct point-to-point connections; bridging technology is available that will allow multiple sites to connect.[80] This Internet2 system functions at about 1500 MHz and is available at most Level 1 educational institutions and some businesses.[81] Although one could construct a similar technology infrastructure, one also could simply create partnerships or negotiate a license for limited access at colleges and businesses.[82] Additionally, videophones could be used immediately to support mediations within RID's Ethical Practices System without having to develop an independent infrastructure.

Finally, Communication Service for the Deaf (CSD) is a non-profit agency serving Deaf and hard of hearing people in offices located across the country. They currently use videoconferencing systems for point-to-point connections. These systems also can be used in the EPS. The CSD videoconferencing systems use Polycom systems or IP-based systems using h.323-based technology.[83] The Polycom PVX system is a personal video conferencing solution that extends the quality of h.323 videoconferencing to the user's PC and webcam.[84]

A. Recommendations for the RID Ethical Practices System

Certain communities and populations are well positioned to integrate more technology into their dispute resolution processes. The Deaf Community is one of those communities. While it is important to identify communities that are prepared to increase their reliance on technology, that identification should not end the inquiry. It also is important to take the next step and provide specific examples of how technology can improve a community's dispute resolution process. This section describes the RID Ethical Practices System and then makes recommendations as to how technology can improve those practices concerning intake, mediation and adjudication

i. Intake

There are several ways in which technology could improve the intake process. First, the initial stage of intake would be improved if greater information about the EPS, including the EPS manual, was provided in ASL and in a video format. Second, notice that is currently sent via post to inform parties about whether a complaint is accepted into the system for further processing or is rejected could be more efficient if it is also sent by e-mail.

> Mediations will be most successful when the parties' substantive and procedural interests are addressed as effectively as possible. When the parties have expressed a strong preference for using a particular technology, then a mediator who cannot use that technology is not the appropriate person to assist those parties.

a. Recommendation One

Complainants typically access the EPS Policy and Procedures manual online via the RID website.[85] Forms can be printed off the website, completed, and sent to the RID National Office, or complainants can videotape responses to the introductory questions and submit their complaint via videotape.[86]

This initial stage would be improved if greater information about the EPS, including the EPS manual, was provided in ASL and in a video format. Video clips of a Deaf person explaining the intake process, the mediation process, and other parts of the manual in ASL would make the information more accessible to a critical target audience. Furthermore, this format also would help alert more potential users that the EPS exists. Video and digitally-based technology would increase consumer awareness and lead to greater utilization of the process.

b. Recommendation Two

When a complaint is received, it is reviewed based upon explicit criteria. The complaint must be based on the possible violation(s) of the official NAD-RID CPC and must be related to the provision of interpreting services.[87] Additionally, it must describe an incident that occurred after the interpreter's services were contracted through a verbal or written agreement and can involve paid or volunteer interpreter service.[88] The complaint may be filed as a result of the contracted interpreter's conduct prior to, during, or after an interpreting assignment."[89] The complaint will either be accepted into the system for further processing (which could include a mediation referral) or rejected.[90] The complainant always is notified by letter as to the disposition and, if the complaint is accepted, then both the complainant and the respondent receive letters explaining the subsequent steps in the process.[91]

Although this approach may be adequate, it could be improved. Because there still are legitimate concerns regarding whether everyone has convenient and affordable access to technology, it may be prudent to continue providing written notice. Sending the notice as a hard copy letter underscores the importance of that information. Additionally, sending a printed letter creates documentary evidence should a question later arise as to whether appropriate notice was provided. Nonetheless, it would be helpful to also send the notice via e-mail or even text message because, assuming that many individuals are like the authors of this article, the mail that receives our attention first every day is our e-mail and text messages, not our postal service delivered paper mail.[92] In addition to initial notice, both the complainant and the respondent should be sent case status updates via e-mail. The updates can be sent as simple textual e-mail messages or can be provided in video form.[93] Furthermore, if an important deadline or significant issue arises, then a person-to-person videophone call may be the most effective medium.

ii. Mediation

The process of mediation could also be vastly improved by technology. First, using the RID website, which includes calendars and other logistical services, can be helpful in coordinating the schedules of the two parties, a mediator, and anyone else who is involved in the process. Second, the EPS manual, which parties are encouraged to review thoroughly before a mediation, could be available on a website along with internet links to various sites offering tools to help parties prepare for negotiations. Third, necessary logistics for mediators who travel from out-of-state could be vastly improved through the use of technology. Finally, if the parties and the mediator are not in the same location, then final arrangements for settlement will proceed more expeditiously if the Mediation Agreement form is circulated among the parties via e-mail attachment or fax.

a. Recommendation One

Logistics for scheduling mediation sessions currently are coordinated by national office staff or the EPS coordinator.[94] Information is shared via numerous e-mail and phone communications, including both telephone and videophone. Although it is commendable that videophones are used for scheduling, this use is expected. Schedules can be arranged more efficiently if one adds additional tools. Calendars and scheduling demands for each session can be placed in a secure area of the RID website. Passwords then can be sent to each party so that he or she can access the information on demand.

Furthermore, a video introduction in ASL can be added for each case. This introduction could be presented by the mediators themselves. The introduction might simply take the form of a greeting and a personal introduction from the mediators or could serve a much more substantial function. In a typical mediation, after the parties and the mediators are introduced to one another mediators provide an orientation; an explanation as to how the mediation will proceed.[95] Mediators take this opportunity to provide information that usually includes a procedural outline for the session contractual, statutory, and common law confidentiality requirements; and an explanation of the mediators' role and responsibilities.

If the video introduction features the mediator in person, then the video will inform the parties as to

the mediator's appearance and demeanor. The parties will have a clearer image of the person with whom they will be dealing. This introduction may help the parties begin to feel more comfortable and secure about the upcoming mediation session.

A mediator, however, may be uncomfortable personally appearing in a video. If that is the case, then the mediator should consider presenting his or her introduction as an avatar, a three-dimensional person or creature created to "live" in cyberspace.[96] Video and animation technology has advanced to the point that attractive, surprisingly lifelike avatars can be created easily. For an excellent example of an avatar using ASL, albeit in a different context, one should view a video created by Vcom3D and Gallaudet University.[97] Companies such as Inperson allow users to create videos that can be used by anyone with an internet connection.[98] VIDITalk lets users create videos that can be e-mailed or streamed to websites and "virtually any mobile device."[99]

There are several advantages to presenting a video introduction. The introductory video, which will be available on demand, can be reviewed repeatedly by each party to ensure that he or she understands the mediator and is prepared for the upcoming mediation. Although introductions must be tailored to each dispute and the specific parties, much of the information conveyed in an introduction is rather generic. For example, unless there has been a change in the law or ethical requirements regarding confidentiality or the parties have unusual confidentiality requirements articulated in their mediation agreement, that part of the introduction will be fairly standard. Once a video introduction is prepared, the introduction can be saved and edited for future mediations.

One of the dangers of presenting the same information repeatedly in real time is that a mediator might lose track of what he or she has said "this time" and forget that he or she has not provided information that is ordinarily provided. A thorough repeatedly vetted video introduction that is reviewed and adjusted to fit each case would avoid this problem.

Recognizing that the emphasis must be on the parties and the dispute itself does not mean that one should ignore the fact that a reusable editable video introduction could prove to be efficient for the mediator. The temptation and concern is that a mediator will not take the necessary time to review and edit the video to make certain it is not only appropriate, but is as helpful and productive as possible for each unique dispute. This concern is not a reason to abandon the tool—it merely is a caution and a call to be responsible.

The fact that the parties can review the introduction repeatedly will help them become more comfortable with video technology. Additional technologies can be explained and illustrated on the video. A video introduction can remind the parties that mediation is not a punitive process, a perception which could lead to frustration and hinder the process. The notion of using a video introduction for a mediation session may make some mediators aghast. But mediators should not allow their own unfamiliarity or discomfort with technology to deprive parties of the technological tools that serve the parties most effectively and productively.

The authors believe that mediators work hard to listen actively, to identify parties' desires and concerns, and respond to parties' needs. As uncomfortable as a mediator may be when it comes to technology, that mediator should not avoid using tools that may facilitate resolution. If a mediator does not feel competent using a particular technology, but the parties themselves would like to use that technology, then the mediator should seek technical assistance. Such assistance should not compromise the mediation process because the individual who is skilled at using technology need not participate in the mediation or have access to confidential information in order to assist the mediator. The difficult question is what should happen if the mediator cannot find adequate assistance or is unable to master the technology. Mediations will be most successful when the parties' substantive and procedural interests are addressed as effectively as possible. When the parties have expressed a strong preference for using a particular technology, then a mediator who cannot use that technology is not the appropriate person to assist those parties.

Each case must be assessed initially and then continually throughout the process. There will be cases where the parties themselves will want to avoid technology because they are uncomfortable with, inexperienced regarding, or distrustful of technology-mediated communications. The parties should not be forced into TMDR. Mediators must recognize that many members of the Deaf Community are very experienced using technology and often will be receptive to the idea of using technology such as video introductions. If a mediator has reservations, then that mediator should keep in mind that a video introduction does not preclude subsequent real time communications regarding the introduction.

In fact, if a video introduction is used, then it is incumbent upon the mediator to follow up and ensure that his or her message was understood. In this respect, the video introduction offers a wonderful opportunity to identify questions and issues, explore those concerns, and answer questions as completely as possible in advance of the formal mediation session. This is preferable to quickly pushing through those concerns on the day of the formal session in a rush to get the "real" mediation session started.

b. Recommendation Two

The EPS manual instructs parties not to prepare evidentiary artifacts or other items that normally would be seen in a courtroom.[100] Parties are encouraged to review the entire manual in preparation for the session.[101] In addition to merely reading the EPS manual, parties also should be encouraged to prepare for the mediation by reviewing their case, clarifying their concerns (their interests), considering their priorities, identifying possible solutions, and noting issues about which they are willing to be flexible and/or compromise. These additional suggestions can be communicated by a brief ASL description on the website, for instance, with internet links to various sites offering tools to help parties prepare for negotiations.[102]

c. Recommendation Three

Participants in EPS mediation sessions include the complainant, respondent and most often two RID mediators. The mediation usually is held in a location convenient for the complainant and respondent. The Deaf Community is relatively small compared to the general population and the EPS system attempts to protect parties' privacy interests and ensure the parties are comfortable with the process. In an effort to achieve these goals, typically mediators from outside the region are retained and all travel expenses are paid by the RID.[103] A mediation session generally is scheduled for an entire day, and occasionally even for two days if the issues appear complex or particularly difficult.

A variety of technologies can be employed to make the process more effective and efficient. As mentioned earlier, the mediator's introduction in ASL can be recorded in video and posted in a secured location on the RID website. The video presentation also can be e-mailed directly to each party. This asynchronous form of communication offers the mediator more time to plan how he or she can communicate concepts clearly and concisely in ASL and provides the mediator with the luxury of erasing and re-recording. If a mediator's introduction is confusing or misleading, then it may establish an unproductive tone for the entire session.

Synchronous tools, such as videoconferencing and bridging technology, can be used to connect the parties and mediators in different locations and allow them to conduct the mediation in ASL. The places where the parties and mediators will be located at the time of the mediation must be determined in advance to ensure that everyone has access to the necessary technologies. Both synchronous activities, such as caucuses, and asynchronous communications can be accomplished using videophones, video e-mail, traditional e-mail, instant messaging, or other appropriate technologies.

Because mediators located outside the region typically are retained in order to protect the parties' privacy interests and to make the parties more comfortable with the process, travel expenses can be significant. Greater reliance on technology can result in significant cost savings.

d. Recommendation Four

When EPS mediation results in a settlement, a Mediation Agreement form is completed by the mediator and signed by both parties.[104] The RID EPS coordinator or designee monitors the terms of the agreement and, when he or she is satisfied, officially closes the case.[105] If an agreement is not reached, then the case is referred to the next step in the EPS, the adjudication process.[106]

If the parties and the mediator are not in the same location, then final arrangements for settlement will proceed more expeditiously if the Mediation Agreement form is circulated among the parties via e-mail attachment or fax. Signatures may be added and faxed back to the RID office or the parties can agree that electronic signatures are sufficiently binding and exchange copies via e-mail. Although not necessary, hard copy originals subsequently can be circulated using the US Postal Service. If an agreement is not reached, then the parties can receive updates via the designated website space for their particular case through videophone or video e-mail. They also can assess whether they would like to continue to mediate the case.

iii. Adjudication

The EPS provides that if a mediation effort is unsuccessful, then a panel of three peer adjudicators will review the original complaint and response and render a final decision.[107] If the panel determines an ethical violation occurred, then it decides what sanctions should be imposed.[108] Generally the adjudicators do not meet with the parties.[109] There are times, however, when additional clarification or information is needed and the adjudicators will schedule a hearing with the parties prior to rendering their decision.[110]

Again, videoconferencing technology, videophones, video e-mail and text-based technology also can be used throughout the adjudication stage. Text-based technology, such as instant messaging, can be used to connect the parties and the adjudicators.

iv. Mediator Support

All of the mediators in the RID Ethical Practices System possess specialized skill and knowledge in ASL, Deaf Culture, and the interpreting process in addition to the skills they possess in mediation and ADR practices.[111] Yet even for these highly skilled individuals, ongoing educational opportunities (and requirements) can improve performance. Although continuing education activities have been offered, these opportunities have been infrequent (probably because of time and cost). Workshops and seminars offered on-line or utilizing distance learning technologies could increase the offerings made available in a cost effective manner.

a. Recommendation One

The RID should use technology to provide more educational opportunities and better support for its mediators. The RID could offer a class to mediators and adjudicators in remote locations by using teleconferencing equipment to support live interaction or they could host a class in a virtual world, such as Second Life[112] or There.com.[113] In these venues the neutrals could join the class as avatars and interact with instructors and each other. This medium would allow neutrals to attend an interactive class from anywhere in the world with internet access. The neutrals would not have to worry about travel costs and the RID would not have to worry about how many individuals will invest travel time and costs. Just as importantly, presenting a class in a virtual world would provide a risk-free opportunity for mediators and adjudicators to experiment and familiarize themselves with virtual world interactions. This experience would help prepare mediators and adjudicators to provide dispute resolution services in a virtual world.[114]

A self-paced online course also could be offered.[115] It could be made more interactive by inviting participants to post messages on a listserv or join a chat room. The RID website can host a secured V-log for mediators and adjudicators where the neutrals can articulate their questions, concerns, or dilemmas and solicit peer support or consultation. Mediators and adjudicators who will be serving on panels can use this technology to meet and prepare for upcoming sessions, exchange information during the proceedings, and debrief afterwards. This technology can be used to provide peer mentoring and support for new mediators and adjudicators who are brought into the system. Video also can be used to provide general information to the public. Videos can be uploaded and shared easily on websites such as Vimeo.[116]

b. Recommendation Two

The RID should consider how it can use technology to improve its support for and delivery of consumer education. Practicing interpreters, students of interpreting, and both non-Deaf and Deaf consumers alike could benefit from information on the website (or accessible on demand in another medium) that addresses specific questions about conflict, conflict resolution and the grievance process. The RID could maintain a Frequently Asked Questions (FAQ) link, for example, similar to the links provided by most commercial retailers operating online. The RID can use technology to distribute and communicate information about conflict management and

resolution and thus empower individuals and entities to resolve conflicts before they escalate into a dispute requiring mediation.

IV. Conclusion

The Deaf Community and the interpreting profession have been affected by technology in immeasurable ways. Deaf people today are communicating in unprecedented manner and frequency. Video-based technologies, for example, allow individuals to communicate across the globe using a natural, visual language.

When interpreters serve as the communication link between Deaf people using ASL and non-ASL users, conflicts can arise and there is a very real need for dispute resolution options. The Ethical Practices System of the RID is an excellent option for resolving disputes that escalate into grievances. Greater reliance on technology, however, can improve the EPS.

Technology allows parties and neutrals to communicate in a variety of mediums quickly and inexpensively. An individual at a remote location can communicate by sending real time video images of him or herself. The videos can be saved and made available on demand. Parties and neutrals can agree to meet in virtual worlds such as Second Life and There.com and present themselves as three dimensional avatars. V-logs, e-mail, instant messaging, and chat rooms can facilitate information exchange and relationship building. The RID can dramatically expand its educational efforts by presenting online continuing education courses for mediators and adjudicators, including support and mentoring services for both new and experienced neutrals. The RID also can create a Frequently Asked Questions (FAQ) link for both consumers and neutrals.

This article addresses a variety of topics ranging from interpreting to ASL and the Deaf Community to ADR and technology, and makes specific recommendations for the RID Ethical Practices System. The recommendations list is not exhaustive. The authors hope that this article will inspire further discussion regarding additional technologies that can be integrated into the EPS and also further conversation regarding the role of technology in other RID programs such as the National Testing System, the Certification Maintenance and Continuing Education programs, and legislative activities.

1 Cynthia B. Roy, Training Interpreters—Past, Present, and Future, in C. Roy (ed.), Innovative practices for teaching sign language interpreters at 10 (2000). Much of the discussion in this article is relevant not only to interpreters working with the Deaf Community, but to interpreters working in any multilingual or cross-cultural environment. This article, however, focuses on American Sign Language (ASL)/English interpreters.

2 *See* David Allen Larson, *Technology Mediated Dispute Resolution (TMDR): A New Paradigm for ADR*, 21 Ohio St. J. On Disp. Resol. 629 (2006); *see infra* note 30 and accompanying text. Technology Mediated Dispute Resolution (TMDR) is a term that Professor David Allen Larson began using in an article published in 2006, Larson asserts that the more commonly used terminology Online Dispute Resolution (ODR) is not sufficiently inclusive and fails to acknowledge the potential of other communication technologies such as cellular telephones, radio frequency devices, and satellite communication systems.

3 *See* http://www.rid.org/UserFiles/File/pdfs/codeofethics.pdf for the complete NAD-RID Code of Professional Conduct. A joint task force of the Registry of Interpreters of the Deaf (RID) and the National Association of the Deaf (NAD) developed this most recent code of professional conduct for professional interpreters.

4 *See* http://www.rid.org/ethics/enforcement_procedures/index.cfm/AID/67 for the flowchart explaining the course for processing a complaint filed with the RID Ethical Practices System.

5 David A. Larson, *Technology Mediated Dispute Resolution (TMDR): Opportunities and Dangers*, 38, U. Tol. L. Rev. 213, 213-14 (2006).

6 *See* Roy, *supra* note 1, at 1–14.

7 Dennis Cokely, *Interpreting Culturally Rich Realities: Research Implications for Successful Interpretations*, RID J. of Interpretation, 1, 4 (2001).

8 Charlotte Baker-Shenk & Dennis Cokely, American Sign Language: A Teacher's Resource Text on Grammar and Culture 65 (1980).

9 Dennis Cokely, *Exploring Ethics: A Case for Revising the Code of Ethics*, RID J. of Interpretation, 25, 27 (2000).

10 *See generally* http://www.rid.org/UserFiles/File/pdfs/EPS_Manual.pdf for the RID Ethical Practices System Policy Manual. (2006) (last viewed August 15, 2007) [hereinafter RID EPS Manual].

11 *Id*. at 1.

12 *Id*. at 2.

13 *Id*.

14 Three motions guided the development and integration of mediation into the EPS. Conference motion C93.07 (1993) reads: "RID establish an ad hoc committee to 1) investigate Ethical Review Mediation Processes, 2) select those that are sensitive to the cultures and communities represented in our society for potential adoption, and 3) assist RID in educating its members and consumers on the use of this Mediation Process." Board motion 96.97 (1996) reads: "[T]o accept Ethical Practices Oversight Committee recommendation #EPO 96.06, to authorize the Association Administrator to pursue funding sources to develop and provide mediation training." Board motion 99.56 (1999) reads: "[T]o accept the Ethical Practices Oversight Committee's listing of roles, responsibilities, members qualification and committee goals. Role: Uphold the integrity of ethical standards among interpreters. Provide technical assistance to the RID Board of Directors as a triad member. Responsibilities: [E]stablish and update the Ethical Practices System Guidelines. Implement the Mediation component of the Ethical Practices System. Oversee the operations of the Ethical Practices System. Provide or coordinate training for the Ethical Practices System. Enhance public awareness of the Ethical Practices System. Serve as liaison for the Ethical Practices Committees. Regularly review and evaluate the Ethical Practices System. Committee member qualifications: [W]orking knowledge of the Code of Ethics. Working knowledge of the interpreting process. Understanding of the grievance process. Understanding of the benefits of mediation. Time commitment: up to two face-to-face meetings per year. Two or more two-hour conference calls. National conference attendance. Ongoing Ethical Practices System training. Access to e-mail and/or fax. Commitment to remain active until mediation is up and running. Other committee goals: [M]ore cultural diversity. Ethical Practices brochure. Increased Deaf membership on committees. National Office staff person for Ethical Practices System. Ethical Practices materials in alternate formats." E-mail from Cheryl Moose, RID President (March 4, 2008) (copy on file with author).

15 Stephanie Criner, Executive Summary, Evaluation project RID's Pilot Mediation Program. Unpublished Manuscript at 6, (2004) (copy on file with author).

16 *See* Ethan Katsh & Janet Rifkin, Online dispute resolution: Resolving conflicts in cyberspace at 23–24 (2001); Susan Summers Raines, *Can Online Mediation be Transformative? Tales from the Front*, 22 Conflict Resol. Q. 437, 437 (2005); David A. Larson, *Technology Mediated Dispute Resolution (TMDR): Opportunities and Dangers*, 38 U. Tol. L. Rev. 213, 213-26 (2006); Lucille M. Ponte & Thomas D. Cavenagh, Cyberjustice Online dispute resolution (ODR) for E-Commerce at 26–27 (2004); Colin Rule, Online dispute resolution for business at 61 (2002).

17 E-mail from Matthew O'Hara, RID Director of Finance and Administration (June 22, 2007) (on file with author).

18 RID EPS Manual, *supra* note 10 at 5.

19 Telephone Interview with Matthew O'Hara, RID Director of Finance and Administration (June 18, 2007).

20 *Id*.

21 *See* RID EPS Manual, *supra* note 10 at 6 (stating that "If the parties decide upon a resolution, the mediators write the agreement and ask both parties to sign. The Mediation Agreement form includes a description of the

agreement, the issue(s) involved in the complaint, and the resolution agreed to by the parties. The resolution should include the points the parties agree on; specific action to be taken by either or both parties; expected completion dates and submission of proof, if required; and terms of compliance.") RID EPS Manual, *supra* note 10 at 7 (noting that "RID will keep a copy of the signed Mediation Agreement".)

22 *Id*. (*noting that* "The RID EPS Coordinator or designee will monitor whether the terms of the Mediation Agreement are satisfactorily completed. Individuals should supply proof that they have met all of the requirements by the completion date.").

23 *Id*. (stating that "when all actions are completed, the case is considered closed.").

24 *Id*. (*explaining that* "RID must receive a copy of the signed Mediation Non-agreement form. The case remains open and is referred to the next step in the EPS, the adjudication process, for review of the original complaint. The circumstances and the results of the mediation attempt are neither provided nor considered in adjudication.").

25 *Id. at 8* (*explaining that* "adjudication is a peer review process in which a selected panel of interpreters evaluates evidence of an alleged violation and determines whether a professional action was in violation of the NAD-RID Code of Professional Conduct. If it is determined that a violation did occur, the panel is further empowered to determine what sanctions should be imposed. A complaint and all supporting documentation are sent to a selected panel of three EPS adjudicators (members of EPS) who review, confer, and make a decision.")

26 *Id*. at 10.

27 For examples of virtual juries, see iCourthouse, http://www.i-courthouse.com (last visited March 16, 2008) and Virtualjury, http://virtualjury.com (last visited March 16, 2008). *See also* Symposium on Enhancing Worldwide Understanding Through Online Dispute Resolution, 38 U. Tol. L. Rev. 1 – 435 (2006) (for a discussion of the many different types of dispute processes that can be offered online ranging from cyberjuries to online mediation, negotiation, and arbitration).

28 *See* Ponte & Cavenagh, *supra* note 16 at 18.

29 *Supra* note 2 at 634.

30 *See* Larson, *supra* note 5 at 213.

31 Any modifications must be transparent. The parties must be able to distinguish the original message from a subsequent modification or supplementation.

32 *See* http://markey.house.gov/docs/telecomm/draft_of_telecom_legislation.pdf.

33 *See* Summary of the "21st Century Communications and Video Accessibility Act." Coalition of Organizations for Accessible Technology (COAT), *available at* http://www.coataccess.org/node/32 (last visited February 4, 2009).

34 Amanda Lenhart, *Data Memo: Cyberbullying and Online Teens*, Pew Internet and American Life Project, 1, June 27, 2007, *available at* http://www.pewinternet.org/pdfs/PIP%20Cyberbullying%20Memo.pdf (last visited March 11, 2008.)

35 *Id*.

36 *Id*. at 4-8.

37 Katsh & Rifkin, *supra* note 16 at 73.

38 *Id*. at 78.

39 *Id*. at 83.

40 *Id*. at 89-90.

41 *Id*. at 74–75.

42 *Id*.

43 *See* Assistive Equipment and Technology fact sheet published by the Minnesota Department of Human Services, Deaf and Hard of Hearing Services Division at http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_003399 (last viewed February 7, 2009).

44 *Supra* note 8 at 246.

45 *Id*. at 246 (noting "[T]here are certain *rules* that people generally follow when using a TTY...: always identify yourself ("PAT JONES HERE" or " THIS IS PAT JONES") since you generally cannot tell who a person is by how s/he types; when you want the other person to respond, type GA ("THIS IS PAT JONES GA) so that the other person knows it is his/her turn to Go Ahead; when you are done with your conversation, type SK or GA (:SEE YOU TOMORROW SK or GA") so the person can decide to stop (SK = "STOP KEY" or continue to respond "GA); conversations are ended by typing SKSK.").

46 *See* Virginia W. Stern & Martha Ross Redden, *Technology and Handicapped People*, Background Paper #2: Selected Telecommunications Devices for Hearing-Impaired Persons (December, 1982) at 9, *available at* http://govinfo.library.unt.edu/ota/Ota_4/DATA/1982/8225.PDF (last viewed February 7, 2009). Despite the antiquated terms used to describe Deaf people, this paper offers an excellent overview of the history and development of TTYs and the subsequent legislation that governed billing for long distance phone usage with TTYs. The Connecticut Public Utilities Control Authority issued an order in 1977 (docket No. *77-0250*, December 16, 1977) allowing a 75 percent reduction in the phone bills of Deaf TTY users for intrastate long-distance calls. Likewise, reductions were initiated in 42 other states during the next four years.

47 *Id*. at 9-10.

48 *See* Larson, *supra* note 29 at 633.

49 *See* TTY Guide from the Minnesota Department of Human Services, Deaf and Hard of Hearing Services Division *available at* http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_004574 (last viewed February 7, 2009).

50 *See* Puneet Gupta, *Short Message Service: What, How, and Where*, Wireless Developer Network (Mindsites Group, LLC 2008) *available at* http://www.wirelessdevnet.com/channels/sms/features/sms.html (last visited February 7, 2009).

51 Andrea M. Braeutigam, *What I Hear You Writing Is . . . Issues in ODR: Building Trust and Rapport in the Text-Based Environment*, 38 U. Tol. L. Rev. 101, 116 (2006).

52 *Id*. at 122. Although Braeutigam's suggestions and insights are valuable, one should be careful about using sensory words indiscriminately.

53 Americans With Disabilities Act, 47 U.S.C. §225. (1990).

54 *See* http://www.fcc.gov/cgb/consumerfacts/videorelay.html (noting that today, interpreters working in VRS Centers are generally referred to "Video Interpreters" or VIs). (last viewed February 7, 2009).

55 Press Release, National Association of the Deaf, NAD President Scoggins Emcees VRS Demo on Capitol Hill (Feb. 26, 2007), *available at* http://www.nad.org/scogginsvrsdemo (last viewed February 7, 2009).

56 *Id*.

57 The number of VRS providers is expanding significantly. Current service providers include: AT&T VRS – www.attvrs.com, California Association of the Deaf VRS – www.cadvrs.com, CSDVRS – www.csdvrs.com, Communication Access Center – www.cacvrs.org, Federal VRS – www.fedvrs.us, Hamilton VRS – www.hamiltonrelay.com, Hands On VRS – www.hovrs.com, Hawk VRS – www.hawkrelay.com, i711 VRS – www.i711.com, IP – VRS – www.ip-vrs.com, Life Links VRS – www.lifelinksvrs.com, My Relay VRS – www.myrelay.com, Nextalk VRS – www.nextalk.net, Snap VRS – www.snapvrs.com, SPRINT VRS – www.sprintvrs.com, Sorenson VRS – www.sorensonvrs.com, Viable VRS – www.viable.net/vrs.

58 *See e.g.* http://www.youtube.com/results?search_query=ASL.

59 *See e.g.* http://www.joeybaer.com/.

60 *See Blog*, Wikipedia, *available at* http://en.wikipedia.org/wiki/Blog (last visited March 28, 2009). Blogs are text-based websites that provide commentary on a wide variety of political to intensely personal issues typically arranged in reverse chronological order. The word blog is a portmanteau of **web log**;

61 *See supra* note 57.

62 Americans With Disabilities Act, 47 U.S.C. §225 (1990). Telecommunications relay services, which are mandated in Title IV, the Telecommunications Title of the American's with Disabilities Act include the provision of video relay services. FCC Consumer Facts, *available at* http://www.fcc.gov/cgb/consumerfacts/videorelay.html (last viewed February 7, 2009).

63 Larson, *supra* note 5 at 218, (quoting Lee Rainie from the Public Library Association's annual conference in March 2006).

64 *See* Jones, *infra* note 66. Yahoo! Groups is a service offered by Yahoo that allows individuals with shared interests to meet in cyberspace and share messages, file, photos and calendars, http://groups.yahoo.com/ (last visited March 16, 2008).

65 *See* http://rid.org/.

66 Angela Jones, What's Technology Got to do With it?, 24 RID Views 4–5 (June, 2007).
67 *Id*. at 4.
68 Julie C. Weisenberg & Emmanuel Garcia, *From Telephone to Dial Tone: A Look at Video Interpreting*. 24 RID Views 32 (June 2007). Weisenberg and Garcia raise concern over the high demand for interpreters in video relay settings by identifying similarities between the experience of artisans during the industrial revolution and interpreters today, drawn to working in video relay centers. "In the world's industrial revolutions, the ones who suffered the most were the artisans, those who were literally crafting and manufacturing products by hand. Then we moved to mechanization in which factories could increase manufacturing rates by using cheap labor. When the artisans were driven out, they became factory workers and fell into routinization and unimaginative assembly line work. We can draw parallels to video interpreting. We have interpreters, who possess a talent for mediating communication and who have traditionally worked in face-to-face situations, moving from the community to machine-based work. Interpreters facilitate calls following specific routines based on the software and equipment for specified periods of time."
69 Katsh & Rifkin, *supra* note 16 at 74.
70 *Supra* note 54.
71 CSDVRS Help Documents and Videos, http://csdvrs.com/support/faq.aspx (last visited February 7, 2009).
72 *Id*.
73 *Id*.
74 *Id*.
75 *Id*.
76 Sorenson VRS Products, http://www.sorenson.com/products/ (last visited April 9, 2009).
77 CSDVRS Frequently Asked Questions, http://csdvrs.com/support/faq.aspx (last visited March 4, 2008).
78 E-mail from John Lange, College of St. Catherine Media Manager (August 13, 2007) (on file with author).
79 *Id*.
80 *Id*.
81 *Id*.
82 Programs within the College of St. Catherine have used the Tandberg 3000 MXP Video Conferencing System in a variety of ways. Both the ASL & Interpreting Department and the CATIE Center have conducted meetings and seminars using this system with Deaf and non-Deaf participants using ASL. The Master of Library and Information Science (MLIS) conducts distance courses for their non-Deaf students in conjunction with Dominican University in River Forest, Illinois.
83 E-mail from Jan Florand, CSD MN Director of Interpreting Operations (August 13, 2007) (on file with author).
84 *See* http://m2l.market2lead.com/go/polycom/pvx_trial_sw (Accessed February 7, 2009).
85 *See supra* note 10 at 2.
86 *Id*.
87 *Id*.
88 *Id*.
89 *Id*.
90 RID EPS Manual, *supra* note 10 at 3.
91 *Id*.
92 First class mail at the Hamline University School of Law, for example, is not delivered to the faculty until after 3:00 p.m. Monday through Friday and the mail is not delivered at all on the weekends. In contrast to this "snail mail" system, e-mail is delivered instantly seven days a week and twenty-four hours a day. Although there can be an occasional lapse in an e-mail system, those delays are addressed quickly and the digital messages then are delivered. The authors suspect that it is unlikely that the percentage of lost e-mail messages exceeds the percentage of paper letters that are "lost in the mail." But more importantly, it would be extraordinarily unlikely that a Complainant's hard copy written notice would be lost or not delivered by the United States Postal Service and that same notice also would be lost or not delivered by an e-mail server. If the goal is to ensure that the Complainant not only receives the notice but does so in a timely manner, then the notice also should be dispatched via e-mail.
93 Video messages can be sent easily and inexpensively. Videos can be created with a simple web camera and sent to the other party or parties as a video mail attachment. Using this method of communication, at least for some individuals, may be faster and more efficient than typing a message. Every communication does not need to be in a video format. But video might be helpful when a particularly complex or potentially confusing message needs to be communicated.
94 *Supra* note 10 at 5.
95 *See* Kimberlee K. Kovach, Mediation: Principles and Practice (West, a Thomson Business 3rd ed.) 160-162 (2004); Carrie Menkel-Meadow, Lela Porter Love, Andrea Kupfer Schneider, Mediation: Practice, Policy, Ethics, 224 (Aspen Publishers, 2006).
96 *See* http://secondlife.com/whatis/avatar.php. (Accessed February 8, 2009). A now familiar example of a virtual environment populated by avatars is Second Life, which describes itself as "an online, 3D virtual world imagined and created entirely by its Residents."
97 "Vcom3D and the Laurent Clerc National Deaf Education Center of Gallaudet University are researching and developing a proof-of-concept system for creating and delivering animated stories using the full range of facial expression and body language of American Sign Language, as well as manual signs. Results from this Phase I proof-of-concept will provide the basis for developing an authoring system and run-time software for creating these animated stories. For this research, we will evaluate how the use of newly developed "Lifelike Expressive Avatars" affects the reading comprehension of Deaf and hard of hearing students. The evaluation tool includes the following story, titled "The Forest", which was written by Jason Stewart, teacher at Kendall Demonstration Elementary School," http://www.vcom3d.com/vault_files/forest_asl/. (Accessed February 8, 2009).
98 *See* Rovion Moving Media, http://www.rovion.com/index.asp.
99 *See* http://www.viditalk.com/site/.
100 *See supra* note 10 at 6.
101 *Id*.
102 *See, e.g.*, http://www.aligncorp.com/images/Align_Negotiation_PrepSheet.pdf;http://tutorials.freeskills.com/negotiation-stage-1-preparation.htm http://ezinearticles.com/?Six-Steps-For-Negotiation-Preparation&id=413338; http://groupmindexpress.com (Accessed February 8, 2009).
103 *See supra* note 10 at 15.
104 *Id*. at 7.
105 *Id*.
106 *Id*.
107 *See* RID EPS Manual, supra note 10 at 9.
108 *Id*.
109 *Id*.
110 *Id*.
111 *Id*. at 5.
112 *See supra* note 96.
113 *See* There.com, *available at* http://www.there.com/ (last visited March 28, 2009).
114 *See* Arno R. Lodder, *Second Life and Other Three Dimensional Visual Worlds: Next Phase for Online Dispute Resolution?* Proceedings of 4th International Workshop on October 5–6, San Jose, USA (2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014845#PaperDownload (last visited February 8, 2009) (discussing the potential for dispute resolution in a virtual three-dimensional environment).
115 Eve Tahmincioglu, *The Faculty Is Remote, But Not Detached,* N.Y. Times, Jobs 15, March 9, 2008, *available at* http://www.nytimes.com/2008/03/09/jobs/09starts.html?_r=1&scp=1&sq=Tahmincioglu&st=nyt&oref=slogin (last visited February 8, 2009) (noting that online courses of all types increasingly are being offered by colleges and universities. Almost 3.5 million students enrolled in online courses in the fall of 2006 and more than two-thirds of all higher education institutions have some type of online offering. Some universities have a truly significant presence online. The University of Phoenix, for example, reports that it has approximately 12,500 online faculty members [primarily part-time]).
116 *See* http://www.vimeo.com/ Similar to YouTube and Google Video, Vimeo allows users to upload, store, and share video. Vimeo distinguishes itself as "the first site to enable High Definition (HD) video sharing." http://www.vimeo.com/press (last visited February 8, 2009).

Physician Profiling: Policy Options to Improve Efficiency in Medicare

*Jackson Williams**

"Profiling may offer promise as a way to rid the health care system of inefficiency—believed by many experts to constitute up to 30% of expenditures.[8] Adoption of these techniques by Medicare, however, will likely provoke conflicts and difficult choices."

I. Introduction

Each year, America's rapidly rising health care costs become the focus of congressional attention as physicians seek relief from Medicare reimbursement cuts. Such cuts are typically mandated by the Sustainable Growth Rate (SGR) formula, intended to hold physician expenditures to a target amount tied to Gross Domestic Product (GDP).[1] Physician expenditures continue to grow excessively relative to GDP,[2] and policymakers are struggling to find a way to contain these costs.

One tool that might be employed is "physician profiling," that is, comparing physicians to each other and using the results in different incentive programs. Health plans and other payors are using episode-grouper software to measure physicians' resource use as one way to profile physicians.[3] Typically, the software groups file claims for services related to a patient's diagnosis, including services provided by the physician, tests and diagnostic work, services provided by specialists, and inpatient and outpatient procedures.[4] The software's programming logic then attributes the resources to a single physician, defines the beginning and end of the episode, and separates out services related to other conditions that the patient may have.[5] The resulting product is a profile that compares the efficiency (and sometimes the quality) of care delivered by different physicians to patients with similar conditions.[6]

Policymakers have discussed possible uses for this information. The least aggressive use of this information is for confidential reporting. Some hope that if physicians become aware of how they compare to others, they will modify their practice pattern.[7] More intrusive uses include public disclosure as a basis for pay-for-performance bonuses or penalties, to place low-resource-use physicians on preferred tiers, and exclude high-resource-use physicians from a network altogether.

Profiling may offer promise as a way to rid the health care system of inefficiency—believed by many experts to constitute up to 30% of expenditures.[8] Adoption of these techniques by Medicare, however, will likely provoke conflicts and difficult choices.

This article will discuss the research findings about variations in physician resource use and how private plans have used claims data to distinguish between efficient and inefficient physicians. It will note some of the conflicts that have arisen from, and challenges involved in, measuring individual doctors' efficiency. Next, the article addresses policy options for Medicare to improve physician efficiency. Finally, it discusses the difference between individual accountability and shared accountability approaches to evaluating physician performance.

II. Background

The rationale for pursuing accountability-based approaches to paying physicians is well stated by the Institute of Medicine (IOM) in the introduction to its report on pay-for-performance, *Rewarding Provider Performance: Realigning Incentives in Medicare*:

> The current Medicare fee-for-service payment system is unlikely to promote quality improvement because it tends to reward excessive use of services; high-cost, complex procedures; and lower-quality care. Through bundled and prospective payment arrangements for institutions, Medicare has attempted to create incentives for efficiencies, but significant price and payment distortions persist.[9]

The National Quality Forum (NQF) has summarized what is at stake:

> Waste in the healthcare system has a negative impact on individual patients and populations. All encounters with the health system expose patients to some degree of risk, and the provision of unnecessary services to patients exposes them to more potential harm than good, not to mention inconvenience and often monetary costs. The provision of unnecessary

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services to patients also consumes resources that could have been used to benefit others in the population (i.e., the uninsured).[10]

It is important to note at the outset that no one expects that efforts to make Medicare more efficient will occur in isolation from efforts to measure and improve clinical quality. Indeed, efficiency is considered one of the six "domains" of quality as defined by the IOM in its seminal report, *Crossing the Quality Chasm*.[11] Technically, efficiency encompasses quality, as it implies a relationship between benefit and cost.[12] However, this article uses the term "efficiency" in the sense of curbing excess resource use, as distinguished from "clinical quality."

Experience in the private sector, as well as studies of Medicare claims, indicate that there is considerable variation in the resources different physicians use to treat similar patients.[13] Private insurance plans have used physician profiling to spur less efficient doctors to emulate their more efficient peers.[14] Policy analysts inside and outside of government urge Medicare to try to alter the behavior of inefficient physicians. As the Medicare Payment Advisory Commission (MedPAC) has argued:

> [T]he nation could spend less on health care, without sacrificing quality, if physicians whose practice styles are more resource-intensive reduced the intensity of their practice—that is, if they provided fewer diagnostic services, used fewer subspecialists, used hospitals and intensive care units as sites of care less frequently, and performed fewer minor procedures.[15]

What is referred to here as the individual accountability approach is heavily influenced by the experience of private health plans with pay-for-performance programs and selective contracting in PPOs.[16] The individual provider is the unit for which performance is analyzed (since the provider could be a group of physicians, the term "individual" is a shorthand expression here). Examples of measures that use providers as the unit of analysis are Medicare's Hospital Compare and Physician Quality Reporting Initiative (PQRI) process measures.[17] It is important to note that the rated physicians may be held responsible for services they may not have furnished or, indeed, for services over which they had little influence.[18]

As the IOM report noted, "efficiency measures are still largely under development."[19] The following discussion clearly indicates that pitfalls await those attempting to implement use of such measurements for individual doctors. Medicare is taking a first, small step in this direction, but several commentators have suggested that further steps should be taken, following the trail blazed by private insurers.

III. Variation in Physicians' Resource Use

A number of studies that use physician practices as the unit of analysis find wide variation in resource use intensity for similar patients, and suggest that the Medicare program would save a substantial amount of money if more doctors adopted the practice styles of those at the high end of the efficiency distribution.

Jonathan Weiner examined three sets of physician claim data to derive risk-adjusted efficiency comparisons, finding that:

> [The] difference in the case-adjusted efficiency between the 30% of physicians that represent the most efficient cohort, and the 30% that are the least efficient, was consistently at least .8 vs. 1.2 of average (average is set at 1.0) for all three databases. This means that the patients of the most 'efficient' group of providers (after case-mix was taken into account) used on average 20% less services than expected while the patients of the least efficient cohort of physicians used services that were 20% more than expected.[20]

MedPAC explored variations in physician resource use utilizing episode-grouper software supplied by commercial vendors.[21] This software allows comparisons of the average resource use of physicians for similar episodes involving similar patients. MedPAC studied variation among several physician specialties and found that for ophthalmologists, dermatologists, internists, cardiologists and allergists, resource use per episode varied twofold or more between physicians in the highest and lowest deciles of intensity.[22]

The Government Accountability Office (GAO) identified "outlier" physicians as generalists who saw a disproportionate share of beneficiaries who accrued medical bills that were unusually high, considering their health status.[23] After taking health status and location into account, GAO found that:

> Medicare patients who saw an outlier generalist—compared with those who saw other generalists—were 15 percent more likely to

> Reporting of efficiency measures may be a double-edged sword—skeptical consumers, left cynical in the wake of perceived managed-care excesses, could view an "efficient" physician as one who skimps on care, and see physicians with more intense resource use as those who are willing to go the extra mile for their patients.

have been hospitalized, 57 percent more likely to have been hospitalized multiple times, and 51 percent more likely to have used home health services. By contrast, they were 10 percent less likely to have been admitted to a skilled nursing facility. We concluded that outlier generalists were likely to practice medicine inefficiently.[24]

IV. Private Plan Activity

A recent report from the Center for Studying Health System Change (HSC) described how private insurers have responded to variations in physician efficiency by identifying "high-performance networks that encourage enrollees to choose network physicians who score well on measures of efficiency and quality."[25] These insurers have used the episode-grouper software to determine whether physicians complied with recommended processes during a treatment episode, as well as the total cost of an episode.[26]

HSC reported that:

> High-performance networks typically are not distinct products, but rather an option for use across different product platforms, most commonly preferred provider organizations (PPOs).
>
> The exact specifications of high-performance networks differ across plans. The most common model uses tiered-provider levels, with corresponding enrollee cost-sharing differentials. The first tier consists of the high-performing providers; the second tier consists of the remainder of in-network providers; and the third tier consists of out-of-network providers. Employers often do not differentiate cost sharing between the first and second tiers, offering these networks only as a source of information to their employees about which providers have better performance.[27]

HSC noted, however, that at least one health plan cut the lowest performing "outlier" physicians from its network altogether, and that another would consider taking this step as well for physicians who fail to change their ways even after receiving specific information on how to improve.[28] Conversely, one prominent insurer, United Healthcare, is paying additional reimbursements to physicians in its top tier.

Based on the private plan experiences, HSC identified several barriers to the operation of tiered networks as follows. First, a perceived lack of legitimacy of efficiency measures is apparent when different data sets, different ranking systems, or different cutpoints result in the same physician being designated as superior by one insurer but not by another, or being designated superior one year but not the next. Variation in scores can be explained by different prices negotiated with different purchasers, yet physician perception of inequities has resulted in pushback.[29] Employers' reluctance to take the heat for the stern measures needed to enforce a tiered network (i.e., telling enrollees they must pay more to see particular physicians, especially when doing so may disadvantage enrollees in particular locations).[30] There was a lack of evidence that tiered networks lower health care costs or inducing widespread change in physician behavior.[31]

While the rollout of individual measures has been rocky, resistance could be expected in an early-adoption phase during which there is a lack of standard measures or benchmarks, disparate insurers analyzing different data, and some clumsiness on the part of insurers in introducing the programs to doctors. Presumably, some of these deficiencies can be overcome by the time that Medicare adopts efficiency measures. On the other hand, as will be discussed below, several real obstacles will provide challenges.

V. Policy Options for Medicare

Implementation of any policies based on physician profiling is complicated first by questions about whether episode-grouper techniques are sufficiently refined to effectively measure physician resource use.[32] Certainly, none have undergone the sort of scrutiny that has been afforded to quality and patient experience measures promulgated by quality promotion organizations such as the NQF or National Council for Quality Assurance. Issues related to accuracy, validity, and risk-adjustment pose unanswered questions.

A. Accuracy issues.

Accuracy issues would include the inability to attribute patients to the appropriate doctor when multiple doctors see the patient, incomplete clinical information in claims data, or an insufficient number of episodes involving a specific condition from which to calculate reliable measures.[33]

B. Validity issues.

Validity issues relate to what constitutes the "correct" intensity of resource use for a given episode. In the absence of evidence as to best practices, benchmarks may be based instead on convenience, such as averages or arbitrary percentiles. Validity, or the perception of validity, can also be hindered by a lack of stakeholder consensus and the opacity of proprietary software programs.

C. Risk adjustment issues.

Measures that do not properly account for the severity of a patient's illness would not only be inaccurate but could also discourage physicians from treating the sickest patients. A separate but similar issue arises from patient behavior that doctors cannot control, such as patients' failure to adhere to treatment plans or healthy lifestyles, inability to afford prescription drugs, or demands for specific expensive services.[34]

Policymakers hoping to spur greater efficiency among physicians delivering care to Medicare patients can choose from a menu of policy options. The options span a continuum that ranges from voluntary and collaborative quality improvement efforts to increasingly rigorous approaches.

VI. Feedback

The mildest policy option is for the Centers for Medicare and Medicaid Services (CMS) to provide confidential feedback to physicians about how their resource use compares with that of peers. The rationale for this option is physician professionalism. As MedPAC observed, "[m]any physicians are highly motivated individuals who have continually strived for high grades and peer approval. If identified as having an unusually resource-intensive style of practice, some physicians may respond by reducing the intensity of their practice."[35] In fact, CMS is already preparing a demonstration project that will use the episode-grouper software to provide feedback to physicians on selected illnesses.[36]

MedPAC also observed:

> Evidence on measuring the effectiveness of resource use in containing private sector costs is mixed and varies depending on how the results are used. Providing feedback on use patterns to physicians alone has been shown to have a statistically significant, but small, downward effect on resource use, but, when paired with additional incentives, the effect on physician behavior can be considerably larger.[37]

MedPAC may be overly optimistic in assuming that providing feedback on resource use with an appeal to doctors' professionalism would have the positive effect that it has in the clinical quality context. First, physicians may disregard feedback viewed as lacking validity and reliability. Second, the appeal of feedback to a doctor's professionalism would have to overcome a very compelling countervailing force: the fee-for-service system's incentive to provide more care. The "target income hypothesis" holds that physicians maintain a volume and intensity of practice sufficient to achieve their preferred balance of profit and leisure.[38]

It may be that the "inefficient" or "outlier" physician is busy, a bit disorganized, and simply has a cavalier attitude toward the use of resources; this physician might be interested in learning about her peers' best practices. On the other hand, she may have a relatively small patient load and "induce demand" for frequent evaluation and management visits or referrals to her own ancillary services, such as imaging, to maintain her standard of living. To be efficient, this physician might have to advertise or take emergency room duty to build a larger patient base, or relocate from an area saturated by a high concentration of physicians to a rural community. The physician may be forced to forgo income necessary to amortize an investment in equipment.

VII. Public Reporting

Further along the incentive continuum is the concept of public reporting of physician efficiency. Efficiency reporting could come to pass by two possible avenues. First, Medicare could take the lead in tabulating and releasing efficiency measures. This approach is embodied in S. 1544, legislation co-sponsored by Senator Judd Gregg (R-NH) and former Senator Hillary Clinton (D-NY) in the 110th Congress.[39] This bill would authorize the creation of Medicare Quality Reporting Organizations which, under contracts with the Department of Health and Human Services (HHS), would publicly release quality and efficiency reports based on Medicare data.[40]

Second, other entities, such as states, public interest groups, or commercial vendors could use Medicare claims data to tabulate and disseminate the information. Consumer advocates had hoped that the claims data needed to measure individual physicians' resource use would be available to the public through the Freedom of Information Act, but a recent court decision has cast doubt on that possibility.[41] It is not clear whether public reporting could begin to move forward without any further legislative or executive action.

"Transparency" has been the focus of several major health care initiatives in recent years, including those of the recent Bush Administration. Measuring and reporting price information was one of the four cornerstones of that administration's Value-Driven Health Care initiative. HHS has already begun posting the prices of various discrete procedures, but has acknowledged that "measur[ing] the overall cost of services for common episodes of care and the treatment of common chronic diseases" is a necessary second step in achieving cost transparency.[42]

A prominent private-sector effort is the Consumer-Purchaser Disclosure Project, which advocates public reporting of efficiency measures as a "path to significant savings in health care."[43] Citing the Weiner research referenced above and other similar research, it contends that "Medicare and other purchasers could save from 2% to 4% of total costs if only one out of ten beneficiaries were to move from less efficient to more efficient physicians."[44] The group has also called for HHS to release Medicare physician billing data to private insurers to enable better comparisons of provider efficiency.

Reporting of efficiency measures may be a double-edged sword—skeptical consumers, left cynical in the wake of perceived managed-care excesses, could view an "efficient" physician as one who skimps on care, and see physicians with more intense resource use as those who are willing to go the extra mile for their patients. For reporting of efficiency measures to have the intended effect, the public must feel assured that "inefficiency" means additional care that provides no marginal benefit.

Progress toward public reporting of efficiency measures is hindered by the concerns over the accuracy, validity, and risk adjustment issues outlined above. These concerns are magnified in the public reporting context because, with reputations and patient relationships at stake, physicians have not hesitated to litigate disputes over these issues. At present, doctors in Connecticut are in court challenging two insurers' designations of superior practitioners as "a fraud upon the public and a libel against the plaintiff physicians" who were not so designated.[45] Doctors in New York State

persuaded the State Attorney General to threaten lawsuits against three insurers planning similar programs,[46] although that dispute has been settled as described below.

Judicial precedents relating to bond-rating agencies suggest that public reporting of physician efficiency ratings would be protected by the First Amendment, even if a court agreed that the ratings were useless to consumers.[47] However, threats of litigation could discourage private entities from taking on this already intimidating task. It is clear that all stakeholders would be better off if a consensus could be reached in advance regarding ways in which to develop resource measures that are accurate, scientifically valid, and do not create perverse incentives for doctors to avoid the sickest patients.

Efforts toward such consensus measures are under way. In early 2007, the Integrated Healthcare Association, a California consortium that pioneered pay-for-performance programs, announced that it would develop efficiency measures to pair with its previously established quality criteria.[48] Later the same year, the Robert Wood Johnson Foundation (RWJF) committed $16 million in grants to build a multiple-payor database to measure and report on physician performance. RWJF said that the project, to be overseen by the Quality Alliance Steering Committee, would:

> [Work] in collaboration with the NQF endorsement process to identify measures of cost for 20 common conditions, resulting in a new set of measures that take into account appropriate use of resources and provide a broader picture of quality of care for these conditions.[49]

Finally, negotiations spurred by the New York State dispute resulted in a multi-stakeholder agreement announced April 1, 2008, which will permit insurer-sponsored performance measurement programs to go forward, subject to review by a "nationally-recognized, independent health care quality standard-setting organization."[50] This "Patient Charter" contemplates scrutiny of heretofore "black box" ranking mechanisms and the eventual development of standards for resource use measurement that will have comparable legitimacy to currently accepted quality measures. However, at least one additional lawsuit has been filed by physicians subsequent to the agreement.[51]

VIII. Tiered Networks

A further step toward applying pressure on physicians would be for Medicare to adopt the tiered network approach that some private plans have taken. In a January 1998 report, the National Academy of Social Insurance's (NASI) Study Panel on Fee-For-Service (FFS) Medicare recommended that Medicare experiment with "best practices of private health plans," including "PPOs, perhaps in which beneficiaries face lower Medicare premiums in exchange for a designated PPO physician."[52] The panel observed that, "[w]ith its large market share and significant data resources, FFS Medicare is in a relatively good position to identify and select preferred providers on the basis of quality or costs."[53]

Eighteen months later, NASI's recommendation was echoed in a Clinton administration white paper on modernizing Medicare. That paper proposed creating a "Medicare Preferred Provider Option," to be administered by "existing organizations with PPOs." To create the PPO network, "practitioners' and providers' claims history and quality information would be assessed. Only those applicants with a demonstrated history of cost-effective medical practice patterns would be selected as preferred providers."[54] Under the Clinton proposal, beneficiaries choosing the PPO option would have lower cost-sharing responsibilities.[55]

Both the NASI and Clinton administration papers cited the prevalence of preferred provider networks in the private sector, but neither addressed what long-term impact they intended a tiered network to have within FFS Medicare. One rationale for tiering doctors is that the variation in resource usage as a given and ask beneficiaries who choose to stay with less efficient doctors to internalize more of the costs that their choice imposes on the program as a whole. However, this approach assumes that patients have made a conscious choice to stick with an inefficient doctor. One question for Medicare in particular is whether there is sufficient access to doctors in the preferred tier. By definition, any preferred provider network limited to a given upper percentile of high-quality, efficient providers will have a limited capacity to absorb patients. Thus, some beneficiaries may be unable to access a top-tier physician because of patient load constraints, not because of choice. For these patients, charging a higher premium or higher co-insurance exacerbates the misfortune they are already experiencing as a result of their inability to access an above-average physician.

Another rationale for tiering would view the preferred provider network not as an end in itself, but as a means for influencing physician behavior. In other words, the ultimate expected outcome would not be a two-tier system, but rather a single tier operating at a higher level of performance, driven by the financial threat to practitioners who do not achieve an acceptable level of efficiency. If this could be accomplished, the inconveniences caused by tiering would be temporary, but would still cause burdens on beneficiaries during a turbulent implementation period.

IX. Payment Tied to Performance

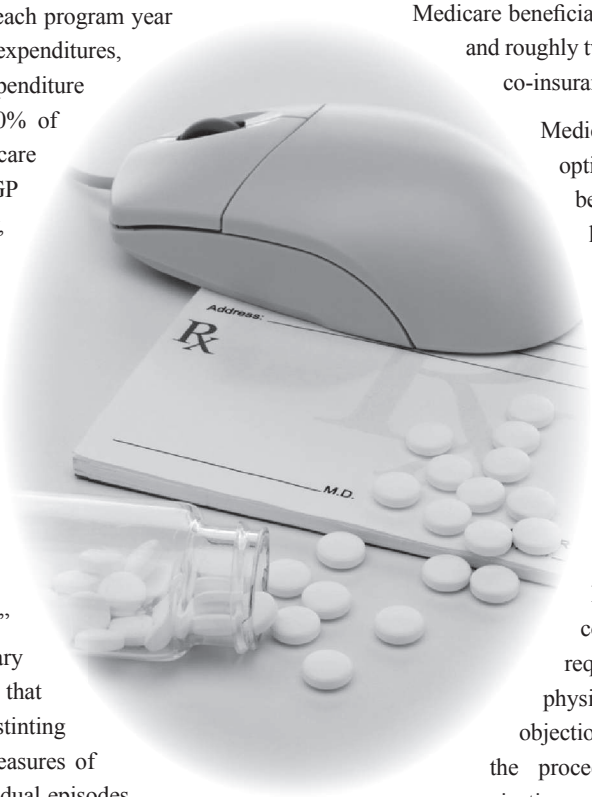
The ideal endpoint of physician payment policy reforms would be an environment in which physicians who provide care of high clinical quality with appropriate resource use are paid more than physicians who provide less value per unit of work. The current system of administered pricing does not allow for differential fees for the most skilled or most efficient doctors. In a pay-for-performance regime, some entity would assess doctors' value and adjust fees accordingly.

Two major pay-for-performance efforts currently underway that reward physicians for both efficiency improvements and clinical quality are the United Health Care (UHC) Practice Rewards program and Medicare's Physician Group Practice (PGP) Demonstration.

The UHC program is based on "episodic efficiency,"[56] with rewards in the form of higher pay. UHC's episode-grouper software sorts physicians along quality and resource use dimensions. It requires physicians first to qualify on the basis of clinical quality as indicated by claims for the provision of guideline-mandated care. After meeting that threshold, physicians are then ranked on resource use.[57] Imagining a grid in which physicians are placed vertically from top to bottom on a quality axis and ranked from right to left on an efficiency axis, physicians lying in the upper right quadrant are eligible for enhanced fees during the year following their designation, receiving a five percent increase to their commercial fee schedule.

As the IOM noted that another option would be to "penalize providers who exhibit the worst performance or the least effort to improve."[58] This could involve withholding some fraction of reimbursements from physicians whose performance does not meet efficiency standards. As the IOM observed, "such a system could generate considerable resistance among providers [and] providers who were not confident of their ability to improve might refuse to participate."[59]

The Physician Group Practice Demonstration is based upon "longitudinal efficiency,"[60] with rewards in the form of shared savings. For each physician group practice (PGP), Medicare savings from the demonstration are calculated by comparing actual spending each program year to the PGP's own base-year per-capita expenditures, adjusted by a comparison group's expenditure growth rate.[61] A bonus pool equal to 80% of savings is created if a PGP achieves Medicare savings of more than two percent. The PGP is entitled to 70% of the pool automatically, but can receive the entire pool of money only if it meets quality targets as well. The PGP model does not "penalize" inefficient resource use, but the provider risks losing any funds invested in improving performance.



A payment methodology that is both "gated" and based on "longitudinal efficiency" might be the most rigorous possible application of efficiency measures to pay-for-performance programs. A "gated" approach making clinical quality a necessary but not sufficient requirement ensures that there can be no backsliding on quality or stinting on care to earn a bonus. Longitudinal measures of care can cut across settings, beyond individual episodes, and over the longer term to promote coordination among the different providers who serve a single patient. By aggregating patients, these measures can also more readily tie rewards to outcomes. This is important because a key efficiency goal is the avoidance of acute episodes through better chronic illness management[62] – an accomplishment that episodic measures may not be able to discern. In addition, analysis solely of an episode's efficiency sheds no light on the question of whether the care was appropriate. An episode of treatment, though "efficient" in the sense of costing relatively little, may have been unwarranted altogether. Finally, longitudinal measures permit shared savings corresponding to the doctor's actual efficiency advantage, rather than an arbitrary reward amount. As Weiner noted, for the top 30% of efficient doctors this can amount to 20% less spending,[63] far exceeding the five percent bonus paid by UHC.

However, unless Medicare providers can be organized into some sort of accountable care organizations similar to physician group practices – on either a mandatory or a voluntary basis – longitudinal measures will be difficult to incorporate into payment methodology. Given the fragmented nature of the practice of medicine, with many solo or small group-based practitioners,[64] episode-based evaluation is more feasible in the existing environment.

X. Prospects

MedPAC staff researchers, recently returned from a series of site visits on the topic, reported to the Commission that health plans see physician resource use measurement as representing "the future" of health care.[65] Certainly, the news that the Integrated Healthcare Association and the QASC are initiating multi-stakeholder efforts as well adds to a sense of inevitability about the concept. The question for policymakers is how to incorporate efficiency measures into Medicare payment policy. Given the unsustainable rate of growth projected for the program, doing nothing is not an option. Inefficient resource use is also an urgent concern for Medicare beneficiaries, who are responsible for Part B premiums and roughly twenty percent of their health care costs through co-insurance.

Medicare has four progressively rigorous policy options. The first option, feedback, will soon be implemented on a pilot basis; proposed legislation in the House would expand it to all doctors. The second option, public reporting, seems to be moving ahead through private efforts. QASC has indicated its intention to issue reports by 2010, although resource use reports could presumably be blocked if the development of efficiency measures fails to achieve consensus support.

Public policy could come into play on public reporting through several circumstances. First, HHS can block access to data by continuing to contest freedom of information requests that seek claims files identifying physicians, or expedite access by lifting its objections. Second, in the event of an impasse in the proceedings of voluntary quality measurement organizations, congressional or agency action could overrule objections and charter an alternative process for endorsing efficiency measurement algorithms. Under the National Technology Transfer and Advancement Act, government policy favors the use of standards set by voluntary consensus bodies such as NQF. But the Quality Advisory Board proposed in S. 1544 provides an example of how NQF could be sidestepped if necessary. Finally, HHS could post efficiency measures on its website, as it has with hospital quality measures.

The third option, tiering Medicare physicians, poses more thorny problems. HSC found that most employers are unwilling to charge workers more to see an inefficient doctor; it would seem all the more difficult for elected officials to impose this discipline on constituents. This option is further complicated by the geographic realities of regional variation in intensity and scarcity of doctors in rural areas. With regard to the former, we know that inefficient physicians are concentrated in certain states.[66] If, as IOM has recommended, physicians are held to nationwide standards, one could imagine a scenario in which the lion's share of a region's doctors are placed in a lower tier, making it difficult for patients to switch. Patients in those regions are already paying higher co-insurance because of the more intense practice styles of their doctors. As a result, they would be punished for their doctors' inefficiency, at least in the short run. If there were no meaningful

opportunity for patients to switch doctors, the intended incentives might not work in the long run, either. Similarly, patients in rural areas might be served by only a few doctors. If all were placed in a lower tier, the patients could have no choice but to pay the higher rate.

Medicare could closely scrutinize "outlier" doctors identified through profiling and exclude from the program those who do not change their practice patterns even after receiving actionable feedback. This could be disruptive to beneficiaries' established relationships with physicians. The effect on beneficiaries depends on how many physicians were excluded from the program – if relatively few were excluded, this could affect existing relationships less than a tiering strategy that placed many physicians on a tier requiring higher cost sharing. Care would need to be taken to ensure that doctors are labeled as "outliers" only because they are truly recalcitrant and not because they serve a particularly ill patient panel. One assumption underlying these physicians' practice style is that they work largely in areas that have a high concentration of physicians.[67] Care needs to be taken to verify this assumption to ensure that patients do not experience access problems as the result of physicians' exclusion.

> "Ultimately, beneficiaries and taxpayers will benefit most from a system that most directly aligns payment with performance."

Ultimately, beneficiaries and taxpayers will benefit most from a system that most directly aligns payment with performance. Achieving this will not be easy. A payment structure that rewards episodic efficiency might miss the bigger picture. MedPAC found that when observed on a per-episode basis, physicians in a high-cost region could appear to be more efficient than those in a low-cost region.[68]

As noted earlier, efforts to assess the resource use of individual physicians face daunting obstacles in terms of accuracy, validity, and risk adjustment. If resource use evaluation indeed represents "the future" of physician payment policy, it will be necessary to design transparent measurement mechanisms that address all such concerns to the reasonable satisfaction of stakeholders. Doctors who have felt aggrieved by efficiency measures have thus far turned to the courts and state attorneys general to overturn private efforts – one imagines that if they felt federal measures were unfair, they would turn to Congress. Policymakers need to keep close watch on the ongoing private-sector efforts to ensure that a public-domain product that can be used by Medicare eventually emerges. If such efforts lag, the Federal Government may have to provide research funding and perhaps a back-up process for certifying efficiency measures so that physician consent to an ultimate NQF imprimatur is not unreasonably withheld.

Among major advantages of individual physician measures are that they would allow the Medicare program and others to learn from physicians who use fewer resources while maintaining a high level of quality. They permit a better understanding of the differences between inappropriate volume growth and appropriate growth (e.g., from technology changes that improve care for patients); they generate information that could be used to identify best practices for the treatment of specified patients and conditions; and they promote individual physician accountability without requiring any large-scale restructuring of the existing physician marketplace.[69]

Perhaps the most serious disadvantage is the difficulty that individual doctors and small-scale practices would face in re-engineering care processes. HSC researchers have described the daunting obstacles overcome by Virginia Mason Medical Center doctors in improving their efficiency when excluded from Aetna's top tier.[70] The HSC findings raise the question: How could smaller provider organizations in non-supportive cultures be expected to implement such sweeping changes if salaried doctors in a large integrated delivery system, supported by leadership trained in the Toyota Production System and working in a community with conservative medical care patterns, endured enormous sacrifices in time and money to achieve efficiencies?

XI. Individual Accountability Versus Shared Accountability

In its report on pay for performance, the IOM argued that a primary goal of new payment incentives should be "to stimulate collaboration and shared accountability among providers across care settings for better patient-centered health outcomes."[71] As noted earlier, physician profiling builds on the assumption that individual physicians should be accountable for resources used in treating their patients.

Physician profiling is an "individual accountability" approach to efficiency, one which respects the traditional autonomy of the physician. In placing the locus of accountability at the individual physician level, it shares the tack taken by the PQRI measures and by the "Medical Home" model that would give primary care physician practices a per-patient-per-month payment, in addition to fee-for-service reimbursements, to coordinate the care of chronically ill beneficiaries.[72]

In contrast, a "shared accountability" approach is inspired by the staff and group models of physician practices associated with health maintenance organizations (HMOs) – although not by the HMO

itself, as it maintains fee-for-service as its basis for payment. "Shared accountability" approaches would apply pressure on individual physicians to act as though they were part of an integrated delivery system. Several leading health policy experts would like to see physicians grouped into "accountable care organizations" or "virtual networks."[73] These approaches are based on the belief that integrated systems are more efficient and better able to coordinate care across settings. Under these proposals, physicians might be placed in pools based upon an "extended hospital medical staff" that reaps bonuses or incurs penalties based on longitudinal measures of quality (such as outcomes) or efficiency of care delivered to the entire population served.[74] Other models, involving "bundled payments," would induce physicians and hospitals to cooperate to improve their efficiency in treating acute episodes by paying (or reconciling payments) *en bloc.*

Because only a relatively small proportion of America's physicians are organized into staff or large group practices, the individual accountability approach is viewed as better able to take the medical practice environment as it is in formulating policy, rather than trying to reorganize it. Thus, PQRI adapts Healthcare Effective Data and Information Set (HEDIS) measures designed for health plans for use at the individual physician level, and physician profiling could, in theory, devolve price competition from the plan level to the individual physician level.

If the preferred attributes of integrated delivery systems—quality measurement, efficiency incentives, and care coordination—can be replicated through either individual accountability programs or shared accountability programs, why would the IOM and many other health policy experts recommend more complex and intrusive shared accountability regimes? Based on an extensive review of research on the subject, Laura Tollen argues that the cohesion, scale, and formal affiliations that characterize organized delivery systems are responsible for their quality and efficiency advantages.[75] She further proposes that seven characteristics of such systems create the dynamics necessary to achieve these advantages: strong physician leadership, organizational culture, clear shared aims, a governance structure, accountability and transparency, selection and workforce planning, and patient-centered teams.[76]

XII. Conclusion

It is immediately apparent that although individual physician approaches may be able to impose transparency and accountability and may pay for creation of patient-centered teams to address chronic illness, they fall short of creating the cohesive peer relationships that would be fostered by the organized, shared accountability model. Physician profiling does create some checks on peers—physicians deemed responsible for an episode have an incentive to refer to high-quality, efficient specialists. On the other hand, some analysts worry that once attribution rules are known, they will be gamed, with PCPs immediately referring out complex patients to specialists.[77] The lack of longitudinal incentives also could allow gaming through the initiation of more episodes.

In contrast, shared accountability proposals require organization and leadership, and, in the case of the accountable care organization, would be likely to spawn governing structures and workforce planning. Other benefits would include increased ability to tie pay to outcomes, increased incentives for providers to coordinate care, and the fact that physician profiling would be overseen by physician peers rather than by the government. Of course, structures created to encourage these benefits would also be potentially vulnerable to gaming.

It should be noted that both the individual and shared accountability approaches are intended to respect physician and patient autonomy by retaining, while restraining, fee-for-service payment. In this regard, the shared accountability proposals fall far short of capitated risk and managed care practices that have troubled physicians and patients alike. When satisfactory measures of individual physician efficiency are implemented, policymakers will have to determine whether Medicare, in making individual accountability rather than shared accountability the norm, would merely be recognizing as inevitable the fragmented nature of care delivery, or would reinforce it.

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California Health Insurance Law Opens the Floodgates for a Potentially Unsustainable Amount of Plastic Surgeries: What Went Wrong and How to Fix It

Adam S. Frankel[*]

I. Introduction

In 1998, after a contentious debate, California became the only state to enact a health care statute broadly mandating insurers to reimburse all surgical procedures that fall within its definition of "reconstructive surgery."[1] There are two pending class action lawsuits alleging that two large insurers are in violation of the California statute by failing to cover certain surgical procedures within its definition of "reconstructive surgery."[2]

Under the current California statute, health care service plans are mandated to reimburse a much greater spectrum of surgeries, including non-medically necessary surgical procedures with the sole purpose of creating an aesthetically "normal appearance."[3] The plaintiffs in the two suits claim the insurers are in violation of the statute by applying a blanket policy of denying reimbursement for all reconstructive surgery claims to remove excess skin following weight loss due to bariatric surgery (a broad term including gastric bypass surgery), a treatment for morbid obesity.[4] This surgical procedure highlights the statute's impermissibly ambiguous construction and illustrates how a common and costly surgery, not falling precisely into the statute's broad definition of reconstructive surgery, is causing conflicts between patients and insurers over what procedures are eligible for insurance coverage.[5]

This article argues that the California legislature delegated an improper amount of discretionary authority to the Department of Managed Health Care (DMHC), the administrative agency tasked to enforce this statute, by allowing unelected agency officials to unconstitutionally exercise legislative power. By failing to draft more instructive standards for the agency to follow, the California statute violates the nondelegation doctrine by assigning legislative lawmaking power to an administrative agency.

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Part II details the difference between reconstructive and cosmetic surgery, outlines the contentious debate over passing the California law, notes the claims made in the first significant pending class action suits brought under the statute's provision defining reconstructive surgery, and introduces the nondelegation doctrine as a method of challenging the constitutionality of overly broad delegations of legislative power. Part III argues that the California statute is unconstitutional for violating the nondelegation doctrine. Part IV suggests several policy recommendations for future health care statutes, and more specifically, recommends that future healthcare statutes not broadly and ambiguously mandate insurance coverage for an expansive class of surgeries and instead, narrowly target the eligible individuals like the Federal Women's Health and Cancer Rights Act of 1998 (WHCRA). The article concludes that the California statute should either be constitutionally challenged because of its impermissibly ambiguous delegation of lawmaking power or amended to allow greater predictability and guidance for the DMHC to follow.

II. Background

A. The Difference Between Reconstructive and Cosmetic Surgery

As surgical procedures become increasingly common avenues of patient treatment regimes and the cost of health care concurrently rises, an inevitable conflict arises between the insurers and patients as to what procedures should elicit insurance coverage.[6] The American Medical Association (AMA) defines cosmetic surgery, not covered under most insurance policies, as surgery "performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem."[7] The AMA defines reconstructive surgery as surgery "performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease" and is "generally performed to improve function, but may also be done to approximate a normal appearance."[8] The California statute's definition of reconstructive surgery and cosmetic surgery closely parallels the

AMA's respective definitions.[9] However, the statute, like the AMA's definition, does not define the meaning of several provisions. Prior to the enactment of the California statute, insurance companies only covered medically necessary procedures. By adopting a standard that allows non-medically necessary procedures for the purpose of creating a "normal appearance," the current law mandates insurers to cover an increasingly large amount of surgeries.[10]

When certain surgical treatments create other conditions that might not functionally impair the patient, problems arise as to the necessary conditions that must be present to receive additional coverage.[11] Given the increasing number of obese Americans, a significant issue for insurers nationwide is whether the surgical removal of excess skin following bariatric surgery for obesity is a covered procedure.[12]

Bariatric surgery, which includes gastric bypass surgery, is now a common treatment option for the disease of obesity.[13] As a result of this increase in the surgery's popularity as well as its improved safety and efficacy, more patients are seeking insurance reimbursement for excess skin removal, claiming the excision of the skin that fails to contract following bariatric surgery is a reconstructive and not a cosmetic procedure.[14]

A problem arises with classifying this surgery as reconstructive under the statute's definition because the excess skin is not caused by a "disease" itself, but rather indirectly by the surgical procedure treating the disease of obesity.[15] Thus, the lawmaker's legislative intent as to whether a disease causes the excess skin is unclear given the statute's nebulous language.[16] Under the current California statute, in order to warrant insurance coverage for the reconstructive skin excision surgery following bariatric surgery, the excess skin must be both an abnormal structure of the body caused by a disease and must either improve function or create a normal appearance, to the extent possible.[17]

B. The Contentious Debate Over the California Law

California is the only state with a law both defining cosmetic and reconstructive surgery and mandating every health care service plan to cover what it defines as "reconstructive surgery."[18] Prior to the current law's enactment, health care service plans that included hospital or surgical benefits covered reconstructive surgery for the purpose of restoring function, but not purely to restore normal appearance as the current law does.[19]

The California Society of Plastic Surgeons (CSPS) lobbied for legislation, citing instances when insurance companies would deny coverage for surgery that would correct physical deformities in patients, often children.[20] The insurers claimed these surgeries were not medically necessary because a person could continue to normally function without undergoing the procedure.[21]

During the legislative debate over this law, an eclectic body of interest groups expressed opinions.[22] Advocates for the bill favored broad coverage of surgeries, stating that insurers should not have the ability to deny coverage of reconstructive surgery to repair physical abnormalities.[23] Advocates were concerned with the trend among insurers to employ cost-cutting measures that they believed negatively affected patient care.[24] Other supporters believed that denying coverage for physical abnormalities may also have a negative psychological impact on the patient.[25]

Opponents of the legislation argued that the bill created an ambiguous order that is extremely difficult to implement.[26] Further, opponents believed that this legislation would make reconstructive surgery susceptible to fraud and would cost an inordinate amount of resources to implement and maintain.[27]

C. An Overview of the Pending California Cases Regarding Health & Safety Code § 1367.63

The two pending class action lawsuits brought under Section 1367.63 of the California statute are before the Superior Court for the County of Los Angeles.[28] The plaintiffs are making identical claims against two large insurance companies.[29] Of the two suits, *Cox v. Health Net of California, Inc.* is further along in litigation so it is the focus of this article's examination.[30]

The first cause of action against the insurers is for breaching their health plan contracts in violation of Section 1367.63 by applying a policy of denying all claims for the reconstructive surgery of excess skin following weight loss from bariatric surgery.[31] The second cause of action is for violating the Unfair Competition Law (UCL).[32]

Although it is uncertain whether these suits will make it to trial, they serve as the first precedents for litigating under this sweeping provision of the statute.[33] In the event that these cases make it to trial and the court interprets the meaning of Section 1367.63, the court will likely have difficulty interpreting and applying the statute's language to specific procedures in determining whether they are reconstructive.[34]

D. Overview of the Nondelegation Doctrine

The nondelegation doctrine is a constitutionally rooted separation of powers principle that prevents the legislature from delegating legislative power to another branch of government.[35] However, beginning in the twentieth century, legislatures at the state and federal level began delegating broad discretionary authority to unelected administrative agencies to regulate complex areas that exceeded the capacity of lawmakers' expertise and was limited by time restraints.[36] As a result of lawmakers' lack of specialized expertise in highly technical areas, legislators write laws deciding the fundamental policy choices, while leaving the agency discretion to craft and implement effective and efficient regulatory laws.[37]

Noteably, the legislature cannot constitutionally vest limitless and ill-defined authority to the administrative agencies and must provide a framework of guiding principles for the agency to follow.[38] This doctrine forces a politically accountable legislature to make policy choices as opposed to appointed administrative officials.[39] The Supreme Court in the modern era has rejected this doctrine and in over sixty years has upheld all delegations, no matter how broad, as proper delegations of authority.[40]

The Supreme Court's nondelegation jurisprudence states that Congress must provide "intelligible principles" in order to guide agencies' exercise of their discretionary authority.[41] By not striking down extremely broad regulatory statutes, the Court has signaled its approval of delegating great discretionary regulatory authority in areas of complex expertise, and also that the Court, like Congress, is ill-equipped to draw the appropriate lines.[42] In *Mistretta v. United States*, Justice Scalia, the only modern advocate of the doctrine sitting on the Court, argued in sole dissent that Congress' delegation

was improper because the U.S. Sentencing Commission possessed broad discretion to make "value judgments and policy assessments."[43] Further, the Court has held it unconstitutional for Congress to transfer legislative functions without imposing procedural safeguards curbing illegitimate exercises of discretionary authority.[44]

The WHCRA is both an example of a constitutional delegation of regulatory power and an instructive paradigm for statutorily mandating insurance coverage for a specific surgical procedure meant to produce aesthetic normality by applying well-defined objective standards not susceptible to impermissibly flexible administrative interpretations.

E. The Federal Women's Health and Cancer Rights Act of 1998

The WHCRA mandates insurance coverage for all stages of breast reconstruction for individuals receiving benefits for medically necessary mastectomies.[45] This coverage extends to surgical procedures solely meant to produce symmetrical appearance, an aesthetic criterion.[46] Additionally, this law does not equate to unrestricted coverage based on a subjective, autonomous decision by the patient.[47] This law, narrowly tailored in its purpose, carefully defines the individuals it seeks to cover and does not broadly mandate coverage for a general area of surgery.[48]

III. Analysis

Despite the reluctance of the judiciary to accept the application of the nondelegation doctrine, California courts should hear a challenge applying the doctrine to the California statute. Although the pending lawsuits are not facial challenges to the law's constitutionality, they may interpret the meaning of "reconstructive surgery" and serve as the first examples of litigation to guide future challenges made under the poorly crafted § 1367.63.[49]

A. The Pending Class Action Suits Serve as Guideposts for Litigating Under the California Statute

The main issue the court must resolve is whether judicial review is currently proper for this case.[50] Health Net, the Defendant insurer, correctly argues that the DMHC has exclusive jurisdiction over this action because the plaintiff's claims call for the determination of Health Net's regulatory compliance with a provision in the Knox-Keene Act.[51] The court in *Schmidt v. Foundation Health* expressed concern noting that when a legislature intends an agency to occupy "completely the field of health service plans," one must be cautious of any intrusion into the agency's function by seeking remedies in other venues.[52] Although the statute is silent on this issue, California case law suggests an individual should have a private right of action in this circumstance.[53]

Although Health Net acknowledges that individuals can sue for acts made unlawful by the Knox-Keene Act, it narrowly reads the act and emphasizes that the law does not specifically outlaw having a policy of refusing to cover the surgical removal of excess skin following weight loss due to bariatric surgery for morbid obesity.[54] Although this plain meaning reading is persuasive, a court will likely follow *Samura v. Kaiser Foundation Health Plan* and read the statute to allow a private right of action because Health Net is accused of the unlawful act of violating § 1367.63 by refusing to cover a surgery falling under its mandate.[55]

Even though a private right of action likely exists, the court will probably not issue a ruling on the legal meaning of "reconstructive surgery" until the DMHC completes its non-routine survey examining Health Net's statutory compliance as the judicial trend gives deference to the expertise of the agency.[56]

Health Net properly invokes the doctrines of judicial abstention and California's primary jurisdiction doctrine in their defense.[57] Employing these legal theories frames the legal debate as a regulatory issue not currently ripe for judicial review.

i. Judicial Abstention is Proper Because the Unique Circumstances of Each Plaintiff's Request is Best Handled by the Statutorily Empowered DMHC

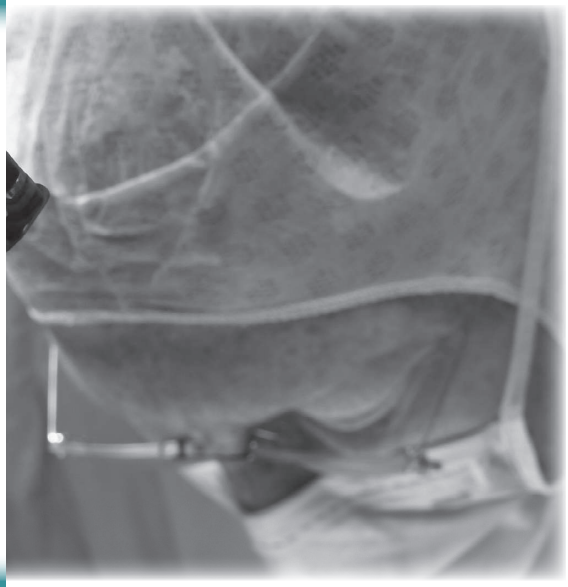
Judicial abstention is proper for this suit because the coverage requests made by each plaintiff within the class action are unique to the facts and circumstances of each request and are most appropriate for the DMHC, experts in health care and tasked to enforce compliance with the statute, to initially determine the insurer's regulatory compliance.[58] Similar to *Alvarado v. Selma Convalescent Hospital*, where the court affirmed the trial court's demurrer to a class action lawsuit that alleged a skilled nursing facility did not adequately provide care for residents, the claims made against Health Net involve complex health care matters where judicial involvement would assume the regulatory function of the agency.[59]

Due to the variety of individual patient pathologies represented in this class action suit and the complex economic and health care implications of issuing broad declaratory and injunctive relief requiring Health Net to cease its alleged 'blanket policy' and to 'review' or 're-review' each claim for coverage as 'reconstructive surgery' under Section 1367.63, the court will likely defer to the DMHC initially to make a conclusion on Health Net's regulatory compliance.[60] Although the DMHC has already ordered Health Net to cover the representative plaintiff's surgery, this order was only for the plaintiff's specific surgery and not for the entire class of plaintiffs as the pending non-routine survey examines.[61]

ii. The Primary Jurisdiction Doctrine is Properly Applied Because the California Statute Delegated Enforcement Power to the DMHC

The California Supreme Court declared that the primary jurisdiction doctrine applies when a plaintiff brings a claim in court but a statute has delegated enforcement to an administrative body.[62] If applied, this doctrine suspends the judicial process until the administrative body reaches a conclusion on the disputed issue.[63] Since the legislature vested exclusive authority in the DMHC and the DMHC is currently conducting a non-routine survey evaluating Health Net's compliance with Section 1367.63, it is the DHMC's statutory duty to complete its evaluation before a court orders injunctive relief.[64]

Thus, as expressed in *Samura*, an individual has a judicial remedy for violations of actions made unlawful under the Knox-Keene Act if the agency tasked to enforce regulatory compliance fails to do so.[65] Since the statute expressly tasks the DMHC to enforce Section 1367.63, individuals should only have a private right of action if administrative redress is incapable of making the plaintiff whole and the DMHC completes its non-routine survey by issuing its final order regarding Health Net's compliance.[66]



Further, if the court holds that all excess skin is an "abnormal structure of the body," and broadly orders insurers to cover its removal regardless of the individual patient's circumstances, it would be deciding a medical policy question that it is ill-equipped to answer.[67] This would set a poor precedent by allowing the statute to become susceptible to manipulation in covering other surgeries not traditionally thought of as reconstructive.

As a result, the DMHC is best qualified to make an initial judgment in this specialized and complex area that will likely lead the court to issue a stay and defer to the agency prior to interpreting the meaning of Section 1367.63 and judicially resolving Health Net's statutory compliance. Although the suits are not facial challenges to the law's constitutionality and will likely only exhibit the difficult application of its language, a challenge under the nondelegation doctrine is one method to invalidate the statute itself.

B. The California Statute Impermissibly Vests the DMHC With the Discretionary Authority To Enforce the Knox-Keene Act Without Providing Sufficiently "Intelligible Principles" to Guide Their Decision Making

Similar to the federal New Deal legislation struck down in *Schechter Poultry Corp. v. United States*, the California legislature cannot delegate its lawmaking authority to another body of government. The California Supreme Court stated that in interpreting a statute, courts should determine the legislature's intent to effectuate the purpose of the law and that laws must not give an administrative agency the ability to exercise greater discretion than is necessary to achieve the law's purpose.[68]

In *Schechter*, the Court recognized the need for regulations focusing on a "host of issues with which the national legislature cannot deal directly," while also acknowledging that Congress cannot individually police every area of regulation.[69] Although it is improper for the California legislature to undermine the necessary regulatory function of the DMHC by enforcing and crafting complex health care regulatory laws itself, it cannot constitutionally delegate total lawmaking power to the DMHC.

The California legislators failed to craft a sufficiently specific enabling act in accordance with the Supreme Court's requisite standard of providing intelligible principles for the DMHC to follow. In order to be reconstructive, the California statute merely requires that the surgery must correct or repair an "abnormal structure of the body."[70] The statute does not define the meaning of abnormal structure and, as a result, consistent application and interpretation by the DMHC, insurers, and physicians as to what conditions constitute an abnormal structure of the body is doubtful.[71]

Further, the statute broadly defines an eligible justification for having reconstructive surgery as to create a "normal appearance, to the extent possible."[72] This language creates an impermissibly flexible and subjective statute susceptible to interpretive problems. By using subjective language like "normal," the legislators removed objective predictability and gave the DMHC virtually unfettered discretionary authority in coverage decisions.[73] This wording creates the possibility for patients to shop around for a doctor who will certify that his/her excess skin is an "abnormal structure of the body" caused by a "disease," and that the surgery should be covered because the removal of excess skin would create more than a minimal aesthetic improvement in achieving a "normal appearance" according to the doctor's personal opinion.[74]

The DMHC, insurers, and physicians need detailed guidance on how to consistently and objectively determine if a patient's requested surgery is reconstructive.[75] Under the statute's current construction, one may argue that a particular procedure is reconstructive surgery even though it only corrects a slight aesthetic abnormality within medically normal ranges.[76]

The statute also fails to define what conditions should be characterized as a "disease" and since there is no uniformly accepted definition as to what constitutes a disease, the DMHC again does not have the necessary "intelligible principles" to determine what conditions the legislature intended to be considered a disease under the statute.[77] The example regarding the surgical removal of excess skin that fails to retract following the

treatment of obesity with bariatric surgery exemplifies the difficulty of classifying whether a disease, under the statute's language, causes certain conditions warranting classification as reconstructive surgery.[78] Arguably, the disease of obesity does not directly cause the excess skin but merely is an unavoidable side effect patients voluntarily accept by undergoing the treatment of obesity with bariatric surgery.[79] In contrast, it is also arguable that the treatment of excess skin is merely a continuation of the treatment of the patient's obesity and as a result, the disease of obesity causes the excess skin.[80]

Like the other provisions in the California statute, the legislators failed to define what constitutes "improve[d] function."[81] Since varying degrees of functional improvements exist, this term is also susceptible to subjective interpretation.[82] For example, although hanging skin can pose problems when it reaches a certain level, not all excess skin poses problems.[83] The sweeping statute is not helpful to allow for individual considerations regarding coverage determinations to a diverse patient population.[84] Arguably, having this excess skin has a negative psychological effect on the patient and, as a result, the surgery is reconstructive because it would improve mental health.[85] In a New York civil court case, the court held that a seventeen-year-old male's surgical excision of enlarged breast tissue was covered under his policy because of the psychological problems caused by the excess breast tissue.[86] By failing to sufficiently clarify whether psychological justifications are alone sufficient for coverage, the legislature again failed to provide the necessary "intelligible principles" for the DMHC to follow.[87]

Although the legislature's intent was to provide eligible individuals with the necessary compensation for surgeries falling under the statute's definition of "reconstructive surgery," by failing to adequately define the necessary conditions that must be present to consistently effectuate this intent, the California legislators violated the nondelegation doctrine by allowing the DMHC to improperly exercise a greater amount of discretion than necessary to fulfill the legislature's intent.

C. The California Statute Impermissibly Vests the DMHC With Discretionary Decision Making Authority Over Complex Policy Questions

By mandating insurance companies to reimburse all procedures under its broad definition of reconstructive surgery, the legislature improperly vested the DMHC with complex policy assessments.[88] Although modern jurisprudence shows an extreme reluctance to strike down regulatory delegations of power, recent case law upholding broad legislative delegations is distinguishable from the subject matter of the California statute. California's jurisprudence states that to prevent unelected agencies from improperly rendering policy decisions, the legislature must utilize a "yardstick" for the administrative agency to follow.[89]

In *Loving v. United States*, the Supreme Court rejected a nondelegation doctrine challenge to the President's prescription of aggravating factors in an Executive Order for the imposition of the death penalty in the military.[90] The Code failed to define the "aggravating" and "mitigating" factors to be considered and as a result, the President exercised discretionary authority by issuing an executive order specifying these factors.[91] Although Loving argued that the President lacked authority to define the aggravating factors enabling the military court to issue a death sentence, the Court rejected the nondelegation doctrine theory emphasizing the long history of the chief executive making rules for the military and noted that it gives Congress great deference in organizing military affairs.[92]

In contrast to the subject matter in *Loving* dealing with the long tradition of giving deference to the executive branch in making military rules, the California legislature's delegation vests unchecked health care regulatory and policy making authority in the hands of an unelected agency.[93] Unlike the President's constitutional action in *Loving*, the California legislature delegated its exclusive constitutionally rooted lawmaking power to an unelected and unaccountable body of administrative officials without adequately clear regulations.[94] The far-reaching language of the statute forces the DMHC to improperly make economic policy judgments by mandating insurers to cover a fiscally unsustainable amount of claims that may have the unintended consequence of causing insurers to provide unaffordable health care plans. As a result of the vast effect this may have on California residents, elected lawmakers, not appointed agency officials, are the proper individuals to make these significant decisions.[95]

In *Kugler v. Yocum*, the California Supreme Court held that the legislature properly made the fundamental policy determination that wages for firemen in one area should be in parity with another and that the delegated power to effectuate this decision was proper.[96] In contrast to *Kugler*, the California legislature failed to make fundamental policy choices and allowed the DMHC to potentially mandate vast insurance coverage for surgeries which may threaten the long term financial vitality of California's health

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> With health care costs taking up a greater percentage of this nation's resources, statutes require more detailed criteria and careful drafting in order to ensure insurers continue to offer affordable coverage that employers will extend to employees.

care system. Based on the vague language chosen by the California legislature in the statute, there is no sufficient "yardstick" in California preventing the DMHC from improperly rendering policy assessments.[97]

D. The California Statute Provides Insufficient Procedural Safeguards to Adequately Curb the DMHC's Discretionary Authority

California jurisprudence suggests that procedural safeguards checking the delegated body's potential abuse of power are more important than substantive regulations in examining the constitutionality of a statutory delegation of power.[98] Further, the California Supreme Court has noted that it is unconstitutional for a legislature to delegate authority without establishing a mechanism to assure the proper implementation of its policy decisions.[99] Although there are minor safeguards within the California statute, the protective checks that limit the exercise of agency discretion are inadequate.[100]

In *California Air Constituency v. California State Air Resources Board*, the California Supreme Court determined that the legislature provided sufficient procedural safeguards that checked the California State Resources Board's discretionary authority to delay a program meant to control automobile emissions.[101] Unlike the enabling act in *State Air Resources* that provided safeguards mitigating the potential abuse of discretionary power, the DMHC has the power to make sweeping coverage conclusions without adequate safeguards checking its discretion.[102]

Under the California statute, if the insurer denies a claim, a patient may challenge the insurer's decision by requesting an Independent Medical Review (IMR) of the health plan's decision to deny coverage under which medical records and other relevant information to the coverage determination are examined by an independent third party.[103] Even if the DMHC approves an IMR and it concludes that the coverage decision deserves compensation, the Director of the DMHC is still the final arbiter and possesses much discretionary latitude in penalizing non-compliance.[104]

Although the statute does not explicitly provide or deny a private right of action or mandate that claimants exhaust their channels of administrative redress under the administrative procedures in place, the barriers to challenge the DMHC's coverage decisions create an almost insurmountable barrier for individual claimants to pursue. In order to receive reimbursement, a claimant can either go through a long administrative grievance system with the ultimate final decision making ability residing in the DMHC's Director, or the claimant can begin a costly litigation battle in civil court against well capitalized insurance companies. Thus, with the onerous and lengthy grievance process currently available to individual claimants, and the fact that insurer's resources dwarf those of individual claimants, the procedures currently in place fail to assure that the DMHC's discretionary power is exercised in a proper and fair manner.

Unlike the Charter Schools Act upheld in *Wilson v. State Board of Education* on the grounds that the legislature properly made fundamental policy decisions and provided adequate safeguards to protect against the State Board of Education's abuse of discretionary power, the California health care statute fails to sufficiently curb the DMHC's discretionary power.[105] Even though the legislative intent is to ensure coverage for eligible individuals that meet the definition of reconstructive surgery set forth in the act, the procedural safeguards set forth by the legislature are insufficient to both successfully implement the statute's intent and to prevent abuse of the DMHC's enforcement power because the safeguards do not provide sufficiently detailed definitions for the DMHC to follow.

In considering whether the statute's procedural safeguards are reasonable, a court will consider the magnitude of the interests affected by the legislative grant of authority.[106] In contrast to the act upheld in *Wilson* that properly delegated discretionary authority to those with the particularized educational knowledge and with a great vested interest in the quality of the educational system, the DMHC is an unaccountable agency tasked to enforce statewide medical insurance decisions that may greatly affect a claimant's greatest asset, life.[107] The DMHC makes health care coverage decisions that determine the available surgical treatment options available to patients and thus individuals affected by the DMHC's regulatory decisions have a much greater personal interest at stake than the state residents and taxpayers challenging the constitutionality of the Charter Schools Act in *Wilson*.[108]

As a result of the statute's insufficiently guiding "intelligible principles," the great policy assessments improperly bestowed upon the DMHC, and the lack of adequate procedural safeguards effectively curbing the DMHC's discretionary authority, the California statute is a fitting example for a constitutional challenge under the nondelegation doctrine. Until a facial challenge to the California law occurs, the pending lawsuits will likely show the law's interpretive difficulties and could put insurers in financially unstable positions creating concern over their future ability to afford covering individuals who are at heightened risk of needing medically indicated surgical procedures in the future.[109]

IV. Recommendations for Future Health Care Statutes

Given the increasingly vast amount of costly procedures that do not fit clearly into either the definition in Section 1367.63 of reconstructive or cosmetic surgery, legislators may learn several lessons from the construction of the statute.[110] If a facial challenge to the law is unsuccessful, legislators should amend the California statute and Congress should not adopt the identical federal bill now before it.[111] This article recommends following the strategies and methods employed by the drafters of the WHCRA and some insurance policies when drafting eligibility criteria for statutes mandating coverage for specific procedures.[112]

With health care costs taking up a greater percentage of this nation's resources, statutes require more detailed criteria and careful drafting in order to ensure insurers continue to offer affordable coverage that employers will extend to employees.[113] Statutes should not contain broad definitions mandating coverage for all reconstructive surgeries but rather only once a certain amount of insurance denials are made for a specific procedure should a statute procedurally require the DMHC or other equivalent administrative agencies to investigate the insurers compliance with the statute. If the agency finds that insurers are not in compliance and believe a specific statute covering a defined surgery (similar to theWHCRA) is appropriate, a process should be created where legislators debate and decide whether to write a law mandating insurance coverage for patients that meet detailed medical eligibility requirements for the specific procedure recommended by the agency.[114]

Under the statute's current construction, virtually any surgical procedure is arguably deserving of coverage.[115] Adopting this proposition would: (1) ensure that legislators are not wasting their time crafting legislation for every rare procedure denied coverage by insurers; (2) save scarce judicial resources by utilizing the expertise of the DMHC or equivalent administrative agencies to make initial but limited coverage determinations; and (3) sufficiently place lawmaking and policy authority in the elected legislature by allowing them to balance the fiscal ability of insurance companies (and indirectly on individual consumers of health care) to cover certain procedures and the desire to follow the agency's recommendation to have specific surgeries universally covered.[116] Once legislators begin drafting the legislation, they should narrowly tailor the language, much like the WHCRA, in order to ensure that only those intended to receive coverage actually do.[117]

Implementation of laws that mandate coverage for reconstructive surgery for the sole purpose of eliciting 'normal appearance' without further guidelines is not advisable. If California lawmakers wish to keep the statute's basic definitions, the legislators should amend the statute to mandate the utilization of an objective method like the Pittsburgh Rating Scale to mitigate the statute's susceptibility to inconsistent and subjective interpretation.[118] Although a physician's treatment decision always holds a degree of subjectivity in deciding the appropriate treatment strategy for patients, the standard currently utilized in California and in the proposed Reconstruction Act of 2007 is greatly susceptible to subjectivity and will necessarily lead to unpredictable results in insurance coverage.[119] The WHCRA is a guiding example requiring an objective basis for determining whether a surgery is coverable.[120]

In contrast to the California statute that employs inherently subjective language like 'normal' and 'abnormal,' the WHCRA uses the word 'symmetrical' to describe the eligibility for reimbursement.[121] Although the WHCRA does not define 'symmetrical' and is not as numerically quantitative as the Pittsburgh Rating Scale, courts can more objectively interpret the popular meaning of 'symmetrical' than the language in the California statute.[122] By selecting a word that has a quantifiable definition, the language chosen in the WCHRA serves as a useful precedent to guide legislators in amending the statute's language.

Another method of solving the statute's deficiencies would be to return to the old law's standard covering only those surgeries that will cause functional improvements. However, if amended, legislators should specifically include psychological functioning in the statute as a sufficient justification for coverage.[123] Adding psychological impairments into the statute's language appeases the law's advocates who noted in the congressional debate that the old law failed to take into account the psychological trauma that accompanies physical disfigurement.[124] Providing authoritative documentation of the physiological or psychological impairment should be required to receive coverage.[125] Since plastic surgeons are not qualified to diagnose psychological afflictions, patients claiming a psychological justification should either obtain a certified psychologist or psychiatrist to diagnose or present a documented psychological difficulty directly caused by their condition.

Lawmakers should also amend the statute to specifically require objective and up to date scientific criteria in making their decisions on: (1) which surgeries elicit functional improvements; (2) whether the condition

"Implementation of laws that mandate coverage for reconstructive surgery for the sole purpose of eliciting 'normal appearance' without further guidelines is not advisable."

is an abnormal structure of the body; and (3) whether the surgery will elicit a normal appearance.[126] Objective criteria and rating systems like the Pittsburgh Rating Scale, should be required to more consistently and accurately determine whether the desired surgery is cosmetic or reconstructive.[127]

V. Conclusion

Although a successful facial challenge to a statute using the nondelegation doctrine has not occurred on the federal level since the New Deal Era, the California statute is a fitting example for employing this doctrine at the state level. The statute unconstitutionally delegates legislative power to an administrative agency by failing to provide adequate guiding principles for the DMHC to follow, by allowing an unelected agency to make complex policy decisions, and by lacking the necessary procedural safeguards needed to curb the DMHC's discretionary authority.

As the line between cosmetic and reconstructive surgery blurs and health care costs make up an increasing amount of our GDP, statutes need more definitive standards for regulatory agencies, insurers, and physicians to follow. The ambiguous California statute, though well intentioned, requires a consistent and accurate method to determine whether the desired surgery is cosmetic or reconstructive as intended by its crafters. Lawmakers need to make a policy choice balancing the need to treat the necessary patients and conserving increasingly scarce economic resources.[128] Even though the California statute is in accordance with the AMA's definitions of reconstructive and cosmetic surgery, its construction is fundamentally flawed in mandating coverage of all procedures within its vague and subjective definition of reconstructive surgery. Health care insurance statutes require objective and precise statutory standards capable of long-term fiscal sustainability as opposed to poorly defined sweeping insurance mandates in order to most accurately and efficiently reimburse patients for the appropriate surgical procedures.

1 *See* Cal. Health & Safety Code § 1367.63(c) (West 1999).

2 *See* Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) (pending in the Superior Court of the State of California for the County of Los-Angeles-Central Civil West).

3 *But see* § 1367.63(e)(1) (noting that if there is a more appropriate surgical procedure, coverage can be denied).

4 *See* First Amended Class Action Compl. for Declaratory & Injunctive Relief at 5, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) (seeking declaratory relief to enjoin Health Net to review or re-review all denials for certain skin excision surgeries).

5 *See* § 1367.63(c) (highlighting that using language like "caused by disease" without providing further guidance creates interpretive problems).

6 *See* Cal. Ass'n of Health Plans, *The Rising Cost of Healthcare: Causes* (2008), *available at* http://www.calhealthplans.com/7press/documents/_Affordability%20Causes.pdf (noting that in 2007, health spending was $2.2 trillion and consumed 16.3 percent of the gross domestic product and by 2017, spending is expected to reach $4.3 trillion taking up an estimated 19.5 percent of the gross domestic product).

7 *See* Am. Soc'y of Plastic Surgeons, *Insurance Coverage: A Patient's Guide* (2008), *available at* http://www.plasticsurgery.org/patients_consumers/planning_surgery/insurance_coverage.cfm [hereinafter A Patient's Guide] (emphasizing that cosmetic surgery is elective and not considered a medical necessity); Am. Soc'y of Plastic Surgeons, *ASPS Recommended Insurance Coverage Criteria for Third-Party Payers: Surgical Treatment of Skin Redundancy for Obese and Massive Weight Loss Patients* (2006), *available at* http://www.plasticsurgery.org/medicalprofessionals/health_policy/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=18091 (distinguishing various types of skin excision surgeries and stressing patients might need various surgeries depending on the symptoms they present).

8 *See A Patient's Guide, supra* note 7 (emphasizing that the surgery's sole purpose may be to improve appearance).

9 *See* § 1367.63(c)(2).

10 *Id*.

11 *See, e.g.*, Pat Speer, *Obesity Surgery Spawns 'New Frontier' for Plastic Surgery*, Plastic Surgery News (2003) available at http://www.plasticsurgery.org/medical_professionals/ publications/obesity-surgery-spawns-new-frontier.cfm (finding after bariatric surgery, an increasing number of patients seek coverage claiming that surgery to remove skin failing to contract is reconstructive).

12 *See* Am. Soc'y of Plastic Surgeons, *Practice Parameter for Surgical Treatment of Skin Redundancy for Obese and Massive Weight Loss Patients*, (2007) *available at* http://www.plasticsurgery.org/medical_professionals/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=24212 (citing that obesity effects fifty eight million people in America causing an explosive demand for bariatric surgery and skin excision following weight loss).

13 *See* Alan Matarasso et al., *Bariatric Surgery: An Overview of Obesity Surgery*, 119 Plastic & Reconstructive Surgery 1357, 1358 (2007) (explaining bariatric surgery reduces the capacity of the stomach and prevents the mixing of food with the digestive enzymes until food is further down the intestinal path); Kim Dixon, *Medicare May Broaden Obesity Payment*, Reuters, May 20, 2008 *available at* http://www.reuters.com/article/healthNews/idUSN1914912220080520 (noting the government may expand coverage for bariatric surgery for the 'obese' and not just the 'morbidly obese' after a study found the surgery can help reverse diabetes).

14 *See generally* Speer, *supra* note 11 (noting the current number of surgeons qualified to operate on weight loss patients is not sufficient to meet the growing demand).

15 *See* T. Oguz Acarturk et al., *Panniculectomy as an Adjuvant to Bariatric Surgery*, 53 Annals of Plastic Surgery 360 (2004) (asserting that excess skin is a common trait of patients who underwent bariatric surgery).

16 *See* Cal. Health & Safety Code § 1367.63(c) (West 1999) (containing a provision explicitly noting that reconstructive surgery must correct an abnormal structure of the body caused by a disease).

17 *But see id.* § 1367.63(e)(2) (stating that if only a minimal improvement in appearance will occur after the requested surgery, denial is appropriate).

18 *Id*. § 1367.63(a).

19 *See* Assemb. Comm. on Ins. Analysis, A.B. 1621, 1997–1998 Reg. Sess., (Ca. 1998) (stating the previous law required plans to cover all medically necessary services).

20 *See* S. Health & Human Services Comm. Analysis, A.B. 1621, 1997–1998 Reg. Sess., (Ca. 1998) (noting the CSPS considers these surgeries a medical necessity).

21 *See* Assemb. Comm. on Ins. Analysis, *supra* note 19 (applying the 'bodily functions' test where if the patient can continue to function without the surgery, coverage would be denied). *See, e.g.*, S. Health & Human Services Comm. Analysis, *supra* note 20 (noting an instance where a girl born without an ear was refused coverage for surgery to construct an ear because the surgery would not restore her hearing and her policy did not cover surgery for restoring normal appearance unless the surgery is primarily to re-establish normal function).

22 *Id*.

23 *Id*.

24 *Id*.

25 *See id.* (denying coverage for individuals who are able to hear but have malformed ears ignores the psychological trauma of physical disfigurements).

26 *See* S. Comm. on Ins. Analysis, *supra* note 20.

27 *See id.* (noting the bill's language could be interpreted to make all reconstructive surgery medically necessary, even elective surgeries like rhinoplasty).

28 *See* Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. filed Feb. 26, 2008) (specifying that the plaintiff in Woelk v. Blue Cross, the other

suit, is alleging that Blue Cross is employing the same statutory violations as Health Net).

29 *See id.* (having the same law firm representing the plaintiffs in both suits).

30 Woelk v. Blue Cross of Cal., Inc., No. BC 391522 (Cal. Super. Ct. filed May 27, 2008).

31 *See* Class Action Compl. for Declaratory & Injunctive Relief at 5, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Jun. 12, 2008) (asserting Health Net violates the statute by improperly claiming that excess skin does not constitute an abnormal structure of the body and/or its removal is not medically necessary).

32 *See id*. at 6 (claiming the insurer's alleged blanket policy constitutes a prohibited act of unfair competition by the UCL which specifically includes any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising).

33 *See, e.g.*, Notice of Demurrer & Demurrer to Compl. of Plaintiff by Health Net of California at 3, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) [hereinafter *Demurrer*] (addressing uncertain issues like whether individuals have a private right of action under the statute); *see generally* Schmidt v. Found. Health, 42 Cal. Rptr. 2d 172, 181 (Cal. Ct. App 1995) (advocating caution in seeking remedies in venues other than those provided by the legislature); Samura v. Kaiser Found. Health Plan, 22 Cal. Rptr. 2d 20, 29 (Cal. Ct. App. 1993) (acknowledging the ability to bring suit to enjoin acts unlawful under the Knox-Keene Act).

34 *See* Plaintiff's Opposition to Defendant Health Net of California, Inc.'s Demurrer to Compl.; Memorandum of Points and Authorities at 4, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) [hereinafter *Opposition to Demurrer*] (stating that the legal issue for the court to resolve is the meaning of "reconstructive surgery" under § 1367.63).

35 *See* U.S. Const. art. I, § 1. (vesting exclusive legislative power in the Congress of the United States).

36 *See, e.g.*, Kugler v. Yocum, 445 P.2d 303, 311 (Cal. 1968) (delegating power to ensure that firemen's wages were in parity with other localities); *see generally* Erwin Chemerinsky, Constitutional Law: Principles and Policies 319 (Richard A. Epstein et. al. eds., Aspen Publishers 2d ed. 2002) (identifying that the rise of the modern administrative state spawned out of the New Deal's programs).

37 *See id.* at 320 (noting the last federal laws declared unconstitutional by the Supreme Court under a nondelegation theory were New Deal legislation exceeding the scope of Congress's commerce power).

38 *See, e.g.*, Mistretta v. United States, 488 U.S. 361, 379 (1989) (upholding a delegation from the legislature to the judiciary for the intricate task of formulating sentencing guidelines because it did not infringe on another branch or improperly expand the judiciary's power); A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 541-42 (1935) (holding that there was an insufficient amount of standards to limit the delegated discretionary authority).

39 *See, e.g.*, Whitman v. Am. Trucking Ass'n, 531 U.S. 457, 475-76 (2001) (upholding a delegation of power to the Environmental Protection Agency to enforce air quality standards because Congress made the fundamental policy decision to regulate air quality while narrowing EPA's discretionary authority by not allowing the agency to consider implementation costs in creating clean air act rules).

40 *See, e.g.*, Loving v. United States, 517 U.S. 748, 773 (1996) (upholding a delegation to the President even without standards limiting discretion).

41 *See Whitman*, 531 U.S. at 472-74 (acknowledging that drafting air quality regulations requires great expertise and noting the commerce clause delegations struck down by the Court did not curb discretion at all).

42 *See* Richard Stewart, *The Reformation of American Administrative Law*, 88 Harv. L. Rev. 1669, 1695-97 (1975) (outlining that if the judiciary strikes down agency decisions, the administrative agencies may lose legitimacy by exposing them to the ongoing threat of judicial invalidation).

43 488 U.S. at 413 (Scalia, J., dissenting); *see* Wilson v. State Bd. of Educ., 89 Cal. Rptr. 2d 745, 759 (Cal. Ct. App. 1999) (finding that the Board of Education was not making policy decisions but merely effectuating the legislature's policy choices).

44 *See, e.g.*, A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 541-42 (1935) (striking down a regulation designed to both ensure poultry quality and regulative employment because it set insufficient standards and in fact delegated virtual law making authority to the President); Air Constituency v. Cal. State Air Res. Bd., 523 P.2d 617, 628 (Cal. 1974) (providing a limited and proper amount of discretionary power to the state resource board).

45 *See* The Federal Women's Health and Cancer Rights Act of 1998, 29 U.S.C. § 1185(a) (1998) (having the attending physician determine if reasonable symmetry is attainable with reconstructive surgery).

46 *See generally* 143 Cong. Rec. S820-01 (1997) (statement of Sen. Snowe) (stating the fear of losing a breast is the leading reason women do not utilize early breast cancer detection programs and covering reconstructive surgery to achieve symmetry is necessary to return to a normal life given the psychological damage of losing breasts to cancer).

47 *See* J.L.F. v. Ariz. Health Care Cost Containment Sys., 91 P.3d 1002, 1005 (Ariz. Ct. App. 2004) (requiring some medically rooted objective support to garner insurance coverage).

48 *See id.* at 1006 (noting that the drafter's intent was to provide coverage for symmetrical appearance if the treating physician believed that undergoing the procedure is supported by sufficiently competent evidence).

49 *See Opposition to Demurrer* at 4, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) (alleging the sole issue in need of judicial resolution is the legal meaning of "reconstructive surgery" under § 1367.63).

50 *See Demurrer, supra* note 33, at 3 (requesting judicial deference to the DMHC because this is a regulatory dispute).

51 *See* § 1341(a) (stating expressly that the DMHC executes the laws relating to health care service plans); Van de Kamp v. Gumbiner, 270 Cal. Rptr. 907, 921-22 (Cal. Ct. App. 1990) (holding that pursuant to the Knox-Keene Act's express grant of authority, the DMHC regulates all aspects of the regulation of health plans including financial stability, organization, advertising and capability to provide health services).

52 *See* 42 Cal. Rptr. 2d 172, 181 (Cal. Ct. App. 1995) (asserting that administrative agency's interpretation of its own regulation deserves great weight).

53 *See* Kasky v. Nike, Inc., 27 Cal. 4th 939, 950 (Cal. 2002) (noting that a plaintiff may bring a UCL action even when conduct violates a statute for the direct enforcement of which there is no private right of action).

54 *See Demurrer, supra* note 33, at 5-6 (stating the plaintiff failed to provide the necessary facts involved in each coverage request, and thus has not alleged Health Net committed acts made unlawful by the Knox-Keene Act).

55 *See* Samura v. Kaiser Found. Health Plan, 22 Cal. Rptr. 2d 20, 29 (Cal. Ct. App. 1993) (holding that despite a statutory enforcement scheme, the plaintiff still may sue to enjoin acts made unlawful by the Knox-Keene Act).

56 *But see* Reno v. Baird, 18 Cal. 4th 640, 660 (Cal. 1998) (finding that although an agency's decision is significant, statutory interpretation is an issue of law fit for a court).

57 *See* Alvarado v. Selma Convalescent Hosp., 153 Cal. App. 4th 1292, 1295 (Cal. Ct. App. 2007) (requiring a trial court to become involved in an agency's duty to regulate complex health care issues is a proper circumstance for judicial abstention).

58 *See, e.g.*, Cal. Health & Safety Code § 1346 (West 1999) (detailing the broad powers that the Director of DMHC possesses to ensure compliance with the statute).

59 *See Alvarado*, 153 Cal. App. 4th at 1298 (indicating that abstention is also proper where injunctive relief would be unnecessarily burdensome to monitor and enforce or where enforcement elsewhere would be more effective).

60 *See* Defendant Health Net of California, Inc.'s Notice of Motion and Motion for an Order to Stay the Action, or Alternatively, to Dismiss Action Without Prejudice at 6, Cox v. Health Net of Cal., Inc., No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) [hereinafter *Motion to Stay*] (observing that the DMHC's Technical Assistance Guide for the Focused Survey on Reconstructive Surgery was created to ensure plan compliance with § 1367.63 and is currently being used by the DMHC in conducting a non-routine survey of Health Net's compliance).

61 *Demurrer, supra* note 40, at 3.

62 *See* Farmers Ins. Exch. v. Superior Court, 826 P.2d 730, 739 (Cal. 1990) (enunciating that the doctrine advances two policies: enhancing judicial decision making and efficiency by taking advantage of agency expertise and helping ensure uniform and predictable application of regulatory laws).

63 *See, e.g.*, Jonathan Neil & Assoc., Inc. v. Jones, 94 P.3d 1055, 1063-63 (Cal. 2004) (holding the doctrine of 'primary jurisdiction' was proper and issued a stay until the California Department of Insurance interpreted insurance rules).

64 *See, e.g., Alvarado*, 153 Cal. App. 4th at 1303 (adjudicating a class action case would assume regulatory power over the health care industry through the guise of enforcing the UCL).

65 *See* Samura v. Kaiser Found. Health Plan, 22 Cal. Rptr. 2d 20, 31 (Cal. Ct. App. 1993) (finding that although the plaintiff had certain remedies, the trial court erred in assuming regulatory power over health maintenance organizations).

66 *See, e.g.*, Cal. Health & Safety Code § 1391 (West 2000) (detailing that if a cease and desist order is issued and a timely request for a hearing is made, the order is stayed until a hearing occurs, and also that every final order of the DMHC is subject to review in accordance with the APA and or judicial review); *see also Motion to Stay*, Cox v. Health Net of Cal., Inc. at 9, No. BC386181 (Cal. Super. Ct. Feb. 26, 2008) (noting any review of DMHC's action would be subject to review in accordance with the APA and then judicial review).

67 *See* § 1342(a) (declaring the legislature's intent was to assure the role of the health care professional as the decision maker of patient's health needs); *see also Samura*, 22 Cal. Rptr. 2d at 29-30 (acknowledging that although an individual can sue to enjoin acts made unlawful by the Knox-Keene Act, a court should not interfere in regulatory matters when doing so impermissibly encroaches on the legislature).

68 *See* Cal. Toll Bridge Auth. v. Kuchel, 251 P.2d 4, 8-10 (Cal. 1952) (holding the California Bridge Authority improperly exercised legislative power not necessary to achieve the law's purpose).

69 A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 530 (1935).

70 *See* S. Comm. on Ins. Analysis, *supra* note 33 (stating the Department of Health Services believes that subjective language hampers regulator's enforcement ability).

71 *See* Irelan v. Standard Mut. Ass'n of Cassville, 379 S.W.2d 815, 824 (Mo. Ct. App. 1964) (finding that unless otherwise noted in the policy, courts apply the popular meaning); *Webster's II New Riverside University Dictionary* 67 (Anne H. Soukhanov ed., Houghton Mifflin Co. 1994) (1984) (defining abnormal as 'deviant').

72 *See* S. Comm. on Ins. Analysis, *supra* note 20 (applying normal appearance standard mandates a much broader and costly scope of coverage).

73 *See* S. Rules Comm. Analysis, A.B. 1621, 1997–1998 Reg. Sess., (Ca. 1998) (stating that taking the language out requiring reconstructive surgery to be 'medically necessary and appropriate' removes health plans power of discretion to deny a procedure given the enrollee's particular condition or if it is too risky for the enrollee).

74 *See* Robert F. Ryan, *The Achilles Heel of Plastic Surgery: Insurance Forms, Fraud, and Loss of Credibility*, 76 Plastic & Reconstructive Surgery 293 (1985) (discussing insurance fraud and noting that some doctors illegitimately cite respiratory obstruction to garner insurance coverage for rhinoplasty).

75 *But see* § 1367.63(b) (attempting to mitigate subjectivity by requiring the surgical judgment to be made in accordance with the standard of care of a trained reconstructive surgeon).

76 *See* S. Comm. on Ins. Analysis, *supra* note 20 (noting that CAHP suggested that under the bill's language, a scar caused by acne or an ear-piercing would be insured irregardless of the fact that the procedures are cosmetic).

77 *See* J.A. Bryant Jr., Annotation, *What Conditions Constitute "Disease" Within Terms of Life, Accident, Disability, or Hospitalization Insurance Policy*, 61 A.L.R.3d 822 (1975) (outlining what courts emphasize in determining whether a condition is a disease under the terms of insurance policies and emphasizing it is an individualized fact specific inquiry).

78 *See* § 1367.63(c) (failing to offer guidance on whether conditions that may result from the treatment of certain diseases are also considered as caused by a disease under the statute).

79 *See, e.g.*, Am. Soc'y of Plastic Surgeons, *ASPS Recommended Insurance Coverage Criteria for Third-Party Payers: Surgical Treatment of Skin Redundancy for Obese and Massive Weight Loss Patients* (2006), *available at* http://www.plasticsurgery.org/medicalprofessionals/health_policy/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=18091 (citing that the largest body of plastic surgeons worldwide believe that when purely to enhance appearance, skin excision is a cosmetic procedure).

80 *See, e.g.*, T. Oguz Acarturk et al., *supra* note 22, at 360 (emphasizing that hanging skin is almost uniformly present in patients who underwent bariatric surgery and that it causes other health problems until excised).

81 *See* § 1367.63(c) (failing to specify if psychological improvements caused by a surgery is a sufficient justification to be become eligible for reconstructive surgery).

82 *See* S. Comm. on Ins. Analysis, *supra* note 20 (discussing the possibility of fraud where patients shop around for a doctor to fraudulently certify that a minimal functional improvement is possible with surgery).

83 *See* Acarturk et al., *supra* note 15, at 360 (noting a dense pocket of fatty tissue usually in the abdominal cavity, called a hanging panniculus, can cause difficulties in movement which in turn may exacerbate the patient's weight and cause recurrent infections).

84 *See also* Reconstructive Surgery Act of 2007, H.R. 2820. 110th Cong. (2007) (introducing a federal bill employing language nearly identical to the California statute and that identical legislation has been introduced in every session of Congress since the 106th in 1999 with no significant movement to become a law).

85 *See* Acarturk et al., *supra* note 15, at 360 (explaining that excess skin can interfere with the psychological well-being and social life of the patient).

86 *See* Steven S. v. GHI, 787 N.Y.S.2d 828 (N.Y. Civ. Ct. 2004) (stating that his avoidance of situations that would expose his condition and subject him to ridicule constituted a functional defect because he was unable to function as a normal adolescent).

87 § 1367.63.

88 *See* Kugler v. Yocum, 445 P.2d 303, 306 (Cal. 1968) (highlighting that while the formulation of policy is a legislative decision, it is proper to delegate the power to fill in the implementation details to administrative officials).

89 *See* Am. Distilling Co. v. St. Bd. of Equalization, 131 P.2d 609, 612 (Cal. Dist. Ct. App. 1942) (clarifying the legislature may not delegate authority that abridges, expands, or modifies the enabling statute).

90 517 U.S. 748, 773 (1996).

91 *See generally id.* at 772-73 (summarizing the Supreme Court's jurisprudence regarding military questions and giving examples of proper delegations of power).

92 *Id*. at 764.

93 *See* Cal. Health & Safety Code § 1341 (West 1999) (prescribing that the DMHC and the appointed Director have the power to execute laws relating to health service plans, the health care service plan business, providing enrollees with access to health care services, and laws protecting the interest of enrollees).

94 *See* Chemerinsky, *supra* note 36, at 323 (suggesting that the Court's refusal to enforce the nondelegation doctrine may undermine government accountability as political decisions are made by unelected officials).

95 *See* S. Appropriations Comm. Fiscal Summary, A.B. 1621, 1997–1998 Reg. Sess., (Ca. 1998) (noting potential increases in both costs to individuals purchasing health care and on the state in the form of higher premiums paid on behalf of public employees and also that the bill will likely cost millions annually).

96 *See* 445 P.2d 303, 311 (Cal. 1968) (holding that an unlawful delegation occurs either when the legislature fails to render basic policy decisions or fails to assure that they are implemented when made).

97 *See, e.g.*, Am. Distilling Co. v. St. Bd. of Equalization, 131 P.2d 609, 612 (Cal. Ct. App. 1942) (finding that certain exercises of discretion by the State Board of Equalization excepting certain chemicals from sales tax were unconstitutional because they resulted in an exception not in accordance with the statute's purpose).

98 Wilson v. State Bd. of Educ., 89 Cal. Rptr. 2d 745, 759-60 (Cal. Ct. App. 1999); *see* 73 C.J.S. *Public Administrative Law and Procedure* § 62 (2008) (emphasizing courts want to assure discretionary power is not unnecessarily or indiscriminately exercised).

99 *Kugler*, 445 P.2d at 306-07.

100 *See* Cal. Health & Safety Code § 1374.30 (West 1994) (outlining the independent medical review process available to those challenging an insurer's denial of coverage).

101 *See* 523 P.2d 617, 628 (Cal. 1974) (holding the provision in dispute which ambiguously empowered the Resource Board by allowing them to consider 'all relevant factors' in assessing the means of implementing the Air Resource Act included only narrow factors directly relating to the three stated goals of the Act).

102 *See id.* (stating any discretionary action by the Resource Board delaying a pollution control program must be justified by directly relating their action to the three specific purposes of the legislation).

103 *But see* § 1374.30(j) (requiring those seeking an IMR to meet specific criteria in order to even qualify for such a review).

104 *See generally id.* § 1374.34 (allowing broad discretion in choosing the method to penalize health plans for non-compliance with the statute).

105 *See Wilson*, 89 Cal. Rptr. 2d at 759-60 (finding the fundamental policy choices by the legislature included giving parents, teachers, and community members the opportunity to set up public schools with operational independence, promoting education innovation and accomplish related public education goals); Cal. Educ Code § 47600 (West 1992) (establishing procedures for individuals to petition local school district governing boards to establish charter public schools).

106 Matter of Powell, 602 P.2d 711, 716-717 (Wash. 1990) (en banc).

107 *See Wilson*, 89 Cal. Rptr. 2d at 759-60 (acting constitutionally by creating a state system of common schools while delegating a proper amount of power to the officers of the public school system to control curriculum, textbooks and operations).

108 *See* T. Oguz Acarturk et al., *Panniculectomy as an Adjuvant to Bariatric Surgery*, 53 Annals of Plastic Surgery 360 (2004) (outlining the variety of serious physiologic and psychological effects hanging skin may have on patients who underwent bariatric surgery).

109 *See* S. Comm. on Ins. Analysis, *supra* note 20 (finding the California Manufacturers Association and Californians for Affordable Health Reform believe that this statute may cause present and potential employers to drop or never consider adopting health plans).

110 *See* Alan Matarusso et al., *Bariatric Surgery: An Overview of Obesity Surgery*, 119 Plastic & Reconstructive Surgery 1357, 1360 (citing that in 2005, 144,000 individuals had bariatric surgery and an estimated 170,000 in 2006).

111 *See* The Reconstructive Surgery Act of 2007, H.R. 2820 110th Cong. (2007) (clarifying that as of the date of this publication, legislators have not yet introduced a new version of this law).

112 *See, e.g.*, Shawkat Sati & Sonal Pandya, *Should a Panniculectomy/ Abdominoplasty After Massive Weight Loss Be Covered by Insurance?*, 60 Annals of Plastic Surgery 502, 504 (2008) (listing an example of some insurance guidelines for panniculectomy/abdominoplasty which generally include: 1) pannus that hangs below level of pubis; 2) patient has had significant weight loss of 100 pounds or more, as well as the following: a. individual has maintained stable weight for at least 6 months, and b. if the individual has had bariatric surgery, they are at least 18 months postoperative; and 3) one of the following: a. if there are recurrent or chronic rashes, infections, cellulites, or non-healing ulcers that do not respond to conventional treatment for a period of 3 months, information must be documented in the records or b. if there is difficulty with ambulation and interference with activities of daily living, information must be documented in office visit records).

113 *See, e.g.*, Jesse T. Nguyen et al., *Reduction Mammaplasty: A Review of Managed Care Medical Policy Coverage Criteria*, 121 Plastic & Reconstructive Surgery 1092, 1098-99 (2008) (outlining that insurance policies require the documentation of the severity and impact on specific quality of life issues to elicit coverage).

114 *See, e.g.*, 28 U.S.C. § 1185(b) (1998) (mandating coverage for breast reconstruction only for those currently receiving coverage for a medically necessary mastectomy and for the aesthetic purpose of achieving a symmetrical appearance).

115 *See* S. Comm. on Ins. Analysis, *supra* note 20 (finding the California Public Employees' Retirement System believed the bill improperly deemed all reconstructive surgery medically necessary).

116 *See* S. Appropriations Comm. Fiscal Summary, A.B. 1621, 1997–1998 Reg. Sess., (Ca. 1998) (noting potential increases in both costs to individuals purchasing health care and on the state in the form of higher premiums paid on behalf of public employees and that because of the statute's mandate, the bill will likely cost hundreds of thousands to millions annually).

117 *See* J.L.F. v. Ariz. Health Care Cost Containment Sys., 91 P.3d 1002, 1006 (Ariz. Ct. App. 2004) (explaining the drafters of the WHCRA intent was to specifically reimburse breast reconstruction to produce symmetrical appearance for individuals receiving coverage for medically necessary mastectomy).

118 *See, e.g.*, Angela Y. Song et al., *A Classification of Contour Deformities after Bariatric Weight Loss: The Pittsburgh Rating Scale*, 116 Plastic & Reconstructive Surgery 1535 (2005) (creating a 10-region, four point grading system that was designed to quantitatively describe common deformities found in each region of the body).

119 *See* S. Comm. on Ins. Analysis, *supra* note 20 (CAHP criticized the use of the words 'normal' and 'abnormal' because these terms, inherently subjective in nature, will necessarily lead to conflict over what is 'normal').

120 *See* § 1185(b) (requiring a physician to certify that the surgery will produce a **measurable** [emphasis added] increase in symmetry and thus resulting in the decreased possibility of unnecessary and costly operations occurring).

121 *See, e.g., J.L.F.*, 91 P.3d at 1003 (stressing the quantifiable nature of achieving symmetry by noting that there was about .5 centimeter difference between the two breasts).

122 *See* Webster's II New Riverside University Dictionary 1172 (Anne H. Soukhanov ed., Houghton Mifflin Co. 1994) (1984) (defining symmetry as "correspondence of form and arrangement of parts on opposite sides of a boundary, as a plane or line or around a point or axis").

123 *See, e.g.*, Steven S. v. GHI, 787 N.Y.S.2d 828 (N.Y. Civ. Ct. 2004) (taking into account the patient's psychological impairments that elicited the need for his surgery).

124 S. Health & Human Services Comm. Analysis, *supra* note 27.

125 *See, e.g., Steven S.*, 787 N.Y.S.2d at 831 (observing that the lack of documentation from a mental health specialist was the apparent reason for his initial insurance denial for surgery).

126 *See, e.g.*, Jesse T. Nguyen et al., *Reduction Mammaplasty: A Review of Managed Care Medical Policy Coverage Criteria*, 121 Plastic & Reconstructive Surgery 1092 (2008) (finding insurance company's policies with respect to a reduction mammaplasty are often arbitrary and not founded upon a scientific basis).

127 *See* Angela Y. Song et al., *A Classification of Contour Deformities after Bariatric Weight Loss: The Pittsburgh Rating Scale*, 116 Plastic & Reconstructive Surgery 1535, 1536 (2005) (stating previous classification systems did not cater to the unique deformities caused by bariatric surgery including the fact that none of the abdominal classification systems have a category for multiple rolls in the pannus which often occurs after bariatric surgery).

128 *See generally* Robert Pearl & Hugh McAllister, *An Economic Analysis of Health Care Reform and Its Implications for Plastic Surgery*, 99 Plastic & Reconstructive Surgery 1 (1997) (finding a decline in plastic surgery's profitability because of an unwillingness to increase health care expenditures by private insurers and the federal government).

FDA Regulation of the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation

*Eloy A. Peral**

I. Introduction

> In Beebe Plains, Vermont, there is a street, appropriately named Canusa Avenue, that runs right along the United States-Canada border. Houses on the northern side of the street are in Canada while houses on the southern side are in Vermont. If a resident of the northern side of Canusa Avenue needs medication to control high cholesterol, he or she can purchase a 90-day supply of 20 milligram Lipitor for $170. On the southern side of the street, Vermont residents will have to dig much deeper if they need to purchase the same drug. The same 90-day supply of Lipitor costs about $330 in the United States.[1]

This is not what one would expect to find in the globalized economy. However, today's global economic system has seen the acceleration of cross-border economic, cultural, and political interactions. These forces have led to a convergence in the price of many goods and services. Due to a host of factors, but especially due to the safety considerations unique to pharmaceutical drugs and the monumental costs needed to protect the public health against unhealthy and ineffective drugs, drugs sold in the United States escape the equalizing effects of the global economy. It is estimated that Americans pay between 35% and 55% more for brand name prescription drugs than people around the world.[2] At a time when health care costs are consuming an increasingly unacceptable share of U.S. Gross Domestic Product (GDP), public pressure has mounted for the use of international market forces in order to lower the price of American prescription drugs. As the government agency tasked with regulating prescription drugs, the U.S. Food and Drug Administration's (FDA) role of ensuring safety and effectiveness is threatened by legitimate demands that health- and life-sustaining drugs become more affordable. The debate on whether to ease the restrictions on the importation and re-importation of drugs reflects a struggle to gain access to cheaper drugs despite the dangers that a relaxation of the FDA's control over drugs will have on public health. Although the importation and re-importation of drugs remains illegal under almost every scenario, otherwise law-abiding Americans are choosing to ignore the law and potential risks associated with consuming drugs that have not received FDA approval. The prospect of alleviating the high cost of health care by purchasing cheaper drugs has even led states to enthusiastically flout federal laws barring importation of unapproved (and thus illegal) drugs.[3]

"At a time when health care costs are consuming an increasingly unacceptable share of US Gross Domestic Product, public pressure has mounted for the use of international market forces in order to lower the price of American prescription drugs."

Due to the explosion of illegal transactions involving the purchase of cheaper drugs in Canada by Americans who seek to transport them into the United States, much of the debate focuses on *re-importation* from Canada and other industrialized nations. Drug re-importation in the United States "involves [Americans] buying American-made prescription drugs from countries to which U.S. pharmaceutical companies export their products, either by traveling there to buy drugs or purchasing them through the mail."[4] Enforcing restrictions on the importation of drugs manufactured in less developed countries, that lack oversight and inspections by an FDA-equivalent government agency, fail to spark the same outcry as the ban on re-importation of drugs from industrialized countries, such as Canada. The FDA frequently cites concerns about the labeling, shipping, and handling of drugs imported from Canada as a policy justification for maintaining the ban on re-importation.[5] The proposition that the Canadian drug supply is less safe has seen effective rebuttals, with some analyses even concluding that it is safer than drugs in the United States.[6] A more convincing reason for prohibiting the re-importation of drugs is that the public health suffers when pharmaceutical companies are discouraged from researching and developing new drugs due to the reduced profitability that would follow re-importation.

This article first provides a summary of the two most accepted explanations for the stark price differential between drugs sold in the United States and those sold in the rest of the industrialized world, specifically in Canada. Second, this article sketches an overview of how the FDA regulates domestic drugs and imported drugs that are FDA approved. Third, this article discusses the law applicable to imported drugs the

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FDA did not approve, and to re-imported drugs that the FDA subjected to its approval process. Finally, this article concludes by briefly analyzing the political variables that may affect the future of drug importation and re-importation.

There are numerous theories advanced to explain why drug prices in the United States and Canada diverge so significantly, even among American-manufactured drugs whose only substantive difference lies in where they are sold. Although no simple explanation exists, the two most common explanations are government drug price controls and price discrimination.

Unlike the market-driven pharmaceutical industry in the United States, Canada's Patented Medicine Prices Review Board (PMPRB) enforces price controls on patented medicines.[7] The PMPRB is an independent arm of the Canadian Government that has the power to "investigate and regulate excessive pricing of patented pharmaceutical drugs," including levying fines if prices exceed the allowable amount.[8] The maximum amount a pharmaceutical company may charge for patented drugs is based on the average price of the drug in seven other developed countries.[9] PMPRB regulations permit patented drug price increases only on a yearly basis, and only if the increase is proportional to an increase in the Consumer Price Index (CPI).[10] The PMPRB estimates that Americans pay 67% more for patented drugs than Canadians do.[11]

Price discrimination may also contribute to the drug price differences and may even supersede price controls as the primary cause.[12] Price discrimination occurs when a company charges different prices in different markets for the same product.[13] Price discrimination is possible when markets are segmented based on certain factors, such as the disposable income and tastes of consumers.[14] A common example of this phenomenon at work occurs when movie theaters charge a lower price for a movie ticket to seniors and students due to their lower average income relative to the general population. Aidan Hollis, a Canadian economist and proponent of price discrimination as the major factor driving price differences, asserts that pharmaceutical companies set a lower price in the Canadian market than they do in the United States, because of Canadians' lower income compared to that of Americans'.[15]

II. The FDA's Regulatory Framework

The FDA's role as a modern regulatory agency is the result of the Federal Food, Drug, and Cosmetics Act of 1938 (FDCA).[16] Congress amended the FDCA more than one hundred times. Some of the amendments

may be described as "technical and remedial," but the most prominent have significantly altered the way the FDA regulates and have expanded the depth and breadth of the FDA's regulatory authority.[17] A notable example is the Medical Device Amendment, which "transformed its approach to regulation of [medical devices] and substantially enlarged the array of regulatory tools available to it."[18] The FDA's regulatory authority, as originally established by the FDCA, is generally categorized into two concepts: (1) "adulteration," which pertains to the content of a product; and (2) "misbranding," which pertains to the labeling of a product.[19] The majority of enforcement power in the FDCA originates from the adulteration and misbranding provisions. Through amendments to the FDCA, the FDA adjusted the definitions of adulteration and misbranding in order to broaden the scope of the FDA's regulatory role. The statutorily prescribed enforcement remedies available to the FDA include criminal prosecution (in coordination with the Department of Justice) of individuals and firms who commit prohibited acts, injunction against such acts, seizure of adulterated or misbranded goods, and pursuit of civil penalties for some violations.[20] Yet informal remedies "comprise the primary routine enforcement tools of the agency."[21] These tools include recalls, publicity, and warning letters.[22]

A. Overview of FDA Regulations Applicable to Imported and Domestic Drugs

For the FDA to permit the importation of a foreign-manufactured drug, it must comply with the same requirements applicable to domestic drugs in interstate commerce.[23] The FDA's regulation of drugs is appropriately referred to as a "closed" system in which the agency regulates the manufacturing, marketing, and labeling of every drug legally sold in the United

> A more convincing reason for prohibiting the re-importation of drugs is that the public health suffers when pharmaceutical companies are discouraged from researching and developing new drugs due to the reduced profitability that would follow re-importation.

States. Imported and domestic drugs must satisfy five requirements, among others, under the FDCA before they can be legally introduced into interstate commerce.[24] First, a drug is *adulterated*, and thus is prohibited from entering interstate commerce, if it is not produced in accordance with good manufacturing practice (GMP).[25] Even if a drug is not "pharmacologically deficient," it is adulterated if it does not comply with GMP.[26] Second, a drug must not be *misbranded*, "which, among other things, means that the labeling must bear the name and address of the manufacturer, packer, or distributer, and [must] not be false or misleading, and that the drug must be manufactured in an establishment registered with the FDA under FDCA § 510."[27] "Any drug, even a foreign version of an FDA approved drug, will be an unapproved drug unless it meets all U.S. packaging, labeling, and dosage requirements."[28] Third, a drug subject to FDCA § 503(b)(1) will be exempt from FDCA § 502(f)(1), when it is "in the possession of a person . . . regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs,"[29] labeling requirements (e.g., re Rx Only), and includes a package insert in the precise language and format approved by FDA.[30] Fourth, "[a]ny imported drug must be dispensed only upon a valid prescription by a licensed prescriber, and distributed with a pedigree[31] except in the case of a manufacturer or ADR."[32] Lastly, and the most onerous of all the requirements, the FDA must approve the drug itself.[33]

i. The FDA Drug Approval Process

As of 2002 it takes an average of 8.5 years and costs about $500 million to comply with the rigorous FDA drug review process and subsequently bring a drug to the consumer.[34] The financial costs and regulatory risks involved in this review process may help explain the broad gap between the price of drugs sold in the United States and those sold in other countries. The drug development process usually begins in laboratories, where scientists test the effects of chemical compounds involved in the disease whose treatment they seek.[35] The chemicals are then tested in two or more species of animals in order to determine whether they can be safely used in humans.[36] This initial laboratory testing of chemicals is referred to as *preclinical research*.

> If the FDA finds the approach promising and an institutional review board of scientists, ethicists, and health-care specialists approves the sponsor's study protocol, the drug enters a progression of tests in humans. Each new trial phase is predicated on a successful outcome of the previous one: *Phase I studies* test the product for its adverse effects on a small number of healthy volunteers. *Phase II studies* probe the drug's effectiveness in patients who have the disease or condition the product is intended to treat. *Phase III studies* seek to determine the drug's safety, effectiveness and dosage. In these trials, hundreds or thousands of patients are randomly assigned to be treated either with the tested drug or a control substance, most frequently a placebo.[37]

The data gathered from these studies and other information about the drug such as, "what the ingredients of the drug are, the results of the animal studies, the way in which the drug behaves in the body, and how it is manufactured, processed and packaged," are then included in a New Drug Application (NDA).[38] An NDA is a formal proposal to the FDA to approve a new pharmaceutical for sale and marketing in the United States.[39] Applications for generic drugs, "a copy that is the same as a brand-name drug in dosage, safety, strength, the way it is taken, quality, performance and intended use,"[40] come in the form of an Abbreviated NDA (ANDA). These applications are "'abbreviated' because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug)."[41]

ii. Importing FDA Approved Drugs

The FDCA places an additional burden on drug importers by prohibiting the importation of food and drugs that "appear" to be adulterated or misbranded.[42] If FDA field staff at a port of entry determine that an FDA-regulated product "appears" to be adulterated or misbranded, the FDA does not admit the product and issues an Import Alert (Alert). If an Alert is issued, identifying a manufacturer, shipper, grower, importer, or a geographic area, "future shipments of that product will not be allowed to enter the United States, unless the importer demonstrates that the product is in compliance with the FDCA."[43] Thus, Alerts transfer the burden of showing compliance to the importer.[44] Furthermore, Alerts identify products that may be detained based on information *other than the results of physical examination of a sample*.[45] The FDA, through its reference manual for FDA personnel, has interpreted "or otherwise" in the enabling statute [46] to mean ". . . a history of the importation of violative products, or products that may appear violative, or when other information indicates that future entries may appear violative."[47] "Appearance" is not defined by FDA regulations.[48] By law, the Secretary of the

Department of Health and Human Services (HHS) holds discretion over the admissibility of FDA-regulated products offered for import and therefore a decision to refuse admission is not reviewable under the Administrative Procedure Act (APA).[49] FDA regulations do provide for an informal hearing to contest refusal of admission,[50] but testimony offered by the owner or consignee of the product is not mandatory or limiting upon the Secretary.[51]

III. Importation of Unapproved and Reimported Drugs

As noted earlier, foreign versions of FDA approved drugs and re-imported drugs are considered unapproved, and thus are prohibited from being introduced into interstate commerce.[52] Despite the narrow and clearly defined legal avenues by which Americans may legally obtain pharmaceutical drugs unapproved by the FDA, in 2003 "nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million entered the United States from Canada."[53] Yet, notwithstanding vigorous legislative efforts to permit the re-importation of drugs for commercial use, it remains nonexistent and illegal, despite the discretion held by the HHS Secretary to waive the restriction.[54] The current enforcement environment is less restrictive as to the personal importation of unapproved drugs, perhaps because of the widely publicized toll prohibitively expensive drugs place on many Americans.[55]

A. Personal Importation of Unapproved Drugs

There are two ways that currently make it possible for an individual to import unapproved drugs into the United States for personal use: (1) the FDA's enforcement guidelines for U.S. Custom and Border Protection (CBP) officers that arguably creates a de facto exemption for individuals who import or reimport unapproved drugs for personal use;[56] and (2) Section 535 of the 2007 Homeland Security Appropriations Act which prohibits CBP from preventing personal reimporation of drugs from Canada.[57] Primarily due to its greater resources, the CBP is tasked with enforcing the drug laws and policies of the FDA and the Drug Enforcement Agency (DEA).[58] These avenues place formal and informal limitations on the amount of unapproved drugs that an individual can import.

The Controlled Substances Act (CSA) also contains specific provisions which allow individuals to travel internationally with limited quantities of their prescription medications "if: (1) the substance is found in one of the approved 'schedules,' (2) the substance is in its original container, (3) a declaration is made to the United States Customs Service, and (4) use of such substance is permitted by federal and state laws."[59] The CSA limits the amount of the controlled substance that can be imported to 50 dosage units of the controlled substance unless the individual possesses a valid prescription issued by a practitioner in accordance with federal and state law.[60] The general purpose of these provisions is to allow patients to only travel with medication that may be medically necessary for their health.

i. FDA's Personal Importation Policy

The FDCA provides no legal exception for the importation or re-importation of unapproved drugs, regardless of whether the importer is an individual or a business. Notwithstanding the limited exception to personal re-importation from Canada located in the 2007 Department of Homeland Security Appropriations Act, personal importation or re-importation of unapproved drugs, remain illegal. In order to "best protect consumers with a reasonable expenditure of resources," and perhaps as a recognition of the potential public backlash for punishing offenders susceptible to sympathy, the FDA maintains in its Regulatory Procedure Manual a personal import policy.[61] The guidelines permit FDA personnel to "use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user."[62] Elaborating this guidance, the manual states that:

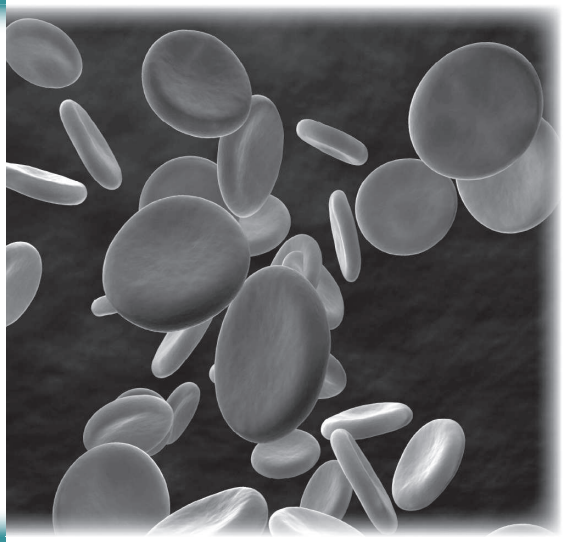
> In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations: (1) when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; and (2) when a) the intended use is unapproved and *for a serious condition for which effective treatment may not be available domestically* either through commercial or clinical means; b) there is *no known commercialization or promotion* to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent *an unreasonable risk*; and d) the individual seeking to import the product affirms in writing that it is *for the patient's own use* (generally not more than 3-month supply) and provides the name and address of the doctor licensed in the U.S.

"The current enforcement environment is less restrictive as to the personal importation of unapproved drugs, perhaps because of the widely publicized toll prohibitively expensive drugs place on many Americans."

> responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.[63]

The guidance does not cover "commercial and promotional shipments" and lists factors such as "the type of product, accompanying literature, size, value, and/or destination of the shipment," that may be used to distinguish between personal shipments and "commercial and promotional shipments."[64]

Although the FDA's enforcement guidelines have been said to create a de facto exemption for individual, non-commercial importation, the guidance states that it "should *not* be interpreted as a license to individuals to bring in such shipments."[65] Despite its clear language, the policy contained in the guidance has been "widely misunderstood and mischaracterized as somehow allowing individuals to bring in any medicines, regardless of the otherwise-applicable import requirements."[66]



ii. 2007 Homeland Security Appropriations Act

Section 535 of the 2007 Homeland Security Appropriations Act prohibits the CBP from preventing individuals "not in the business of importing a prescription drug (within the meaning of section 801(g) of the Federal Food, Drug, and Cosmetic) from importing a prescription drug *from Canada that complies with the Federal Food, Drug, and Cosmetic Act* . . . ."[67] This section essentially permits the re-importation of drugs from Canada that would otherwise comply with FDA standards. This law does provide for important limitations for those who seek to act on this prohibition against enforcement because the section is only applicable to "individuals transporting *on their person* a personal-use of the prescription drug, *not to exceed a 90-day supply* . . . ."[68] These qualifications substantially limit individuals who may exploit this exception to the ban on re-importation. Only individuals who live near the American-Canadian border can benefit from this exception due to the prohibitive cost of traveling from further distances.

B. Commercial Re-Importation

There are no legal or enforcement exceptions permitting the importation of foreign-manufacturer drugs for commercial purposes. There are two conditional exceptions to the prohibition on re-importation: (1) the HHS Secretary has the authority to authorize re-importation if the "drug is required for emergency medical care;" [69] and (2) importation may be allowed under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).[70]

The Prescription Drug Marketing Act (PDMA) of 1988[71] amended the importation provision of the FDCA to prohibit the re-importation of a drug unless the drug is imported by the manufacturer of the drug.[72] The PDMA was a result of a series of hearings held in the mid-1980s by the House Committee on Energy And Commerce "aimed at illuminating flaws in the U.S. drug distribution system."[73] A House oversight report encapsulated the impetus behind the passage of the PDMA:

> The realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origins of much of this merchandise is unknown to the first, second, or third level buyer, who in effect plays a form of Russian roulette. This situation cannot be allowed to continue.[74]

In addition to amending the FDCA to prohibit re-importation by anyone other than the manufacturer of the drug, the PDMA also established minimum federal requirements for the wholesale distribution of drugs, including requiring pedigree papers for certain transactions.[75]

i. The Re-Importation Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA)

The MMA superseded the Medical Equity Drug Safety Act, which had similar import provisions to the MMA. The MMA, which became effective January 1, 2006, was an ambitious and comprehensive response to the high cost of drugs. Although it is

arguably incomplete and severely skewed toward the interests of drug manufactures,[76] it did lead to notable outcomes. The most notable outcome of the MMA was that it added Part D, the Medicare Prescription Drug Benefit, to Title XVIII of the Social Security Act. The program disperses the risk of drug cost by including private insurance plans that contract with the Federal government.[77] The drug coverage is provided through Medicare Advantage prescription drug plans chosen by Medicare beneficiaries.

Indeed, Medicare Part D, as it is commonly referred to, is the most substantial expansion of Medicare ever. Due to its extension of Medicare benefits to prescription drugs, research suggests that the MMA may have led to a decline in importation of drugs from Canada.[78] It has been alleged that the U.S. Government has strengthened enforcement against personal re-importation in order to encourage enrollment in Medicare Part D.[79]

The MMA provides that "The [HHS] Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[80] The MMA then provides requirements that importers and imported drugs must comply with. The MMA also contains a provision allowing the HHS Secretary to authorize waivers for individual importation: "The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate."[81] However, these provisions are ineffective until the "Secretary certifies to the Congress that the implementation of this section will – (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer."[82] To date, all HHS Secretaries since the MMA and its predecessor, the Medical Equity Drug Safety Act became effective have declined to issue certification.[83]

ii. The States Respond

The re-import provisions of the MMA provides states with an uncertain legal window, but a potent political instrument to move forward with state-sponsored drug programs that would give residents access to cheaper re-imported drugs. The MMA prompted states to petition the HHS to grant waivers to permit individuals to re-import drugs from Canada and to issue a certification permitting the commercial re-importation of drugs from Canada. As mentioned before, no waivers or certifications have been issued under MMA and its predecessor. All state efforts to have the MMA legitimize their state re-importation efforts through litigation have also failed. Despite this, states have continued to operate re-importation programs with the aid of Canadian pharmacies.[84]

In 2005, the Vermont Agency of Administration submitted a citizen petition to the FDA requesting that the FDA allow the Vermont State Employee Medical Benefit Plan (VTSEMBP) to "establish a program for the orderly individual importation of prescription medications."[85] In the petition, the State of Vermont explained that it wanted:

> Authority to contract with providers to create a system under which its members have the option of forwarding a prescription to a Canadian firm where the prescription would be reviewed by a physician familiar with the member's medical history and re-written as a Canadian prescription, which would be forwarded to a licensed Canadian pharmacy to be filled and sent by mail to the member in the United States.[86]

The FDA denied this petition. In *Vermont v. Leavitt*,[87] Vermont alleged that the FDA's refusal of a Vermont's citizen's petition was "arbitrary and capricious" in violation of the Administrative Procedure Act (APA).[88] Vermont utilized some creative, yet very unconvincing applications of statutory interpretation to argue that the MMA authorized their program[89] and challenged the constitutionally of the Act by unsuccessfully invoking the non-delegation doctrine.[90] The Defendants claimed that they were required to deny the petition because it proposed a drug importation program that violated federal law.[91] In granting the Defendant's motion to dismiss, the Court held that the MMA could not be construed to authorize Vermont's importation program and that the program would violate 21 U.S.C. section 331(t) by "causing" its members to import drugs in violation of 21 U.S.C. section 381(d)(1).[92]

A year later in *Montgomery County, Md. v. Levitt*, Montgomery County, Md. (County) requested a waiver to allow the residents of the County and its government to import drugs from Canada.[93] The County applied the same arguments used by Vermont, which yielded the same results.[94]

Undeterred, states have persisted in their efforts to facilitate the purchase of cheaper foreign drugs. The most ambitious state leader was former Illinois Governor Milord R. Blagojevich, who created the web site I-Save RX, which also serves residents of Wisconsin, Kansas, Missouri, and Vermont.[95] I-Save

RX uses a Canadian Pharmacy Benefit Management (PBM), which sources the drugs from Canada, Ireland, the United Kingdom, New Zealand, and Australia. "Under the program, US prescriptions and medical histories are forwarded to physicians in the supplying countries, apparently rewritten to comply with local laws, and dispensed by local, licensed pharmacists who then ship the medicine to the United States."[96] The program only applies to refills and excludes most drugs that require special handling.[97] Former Governor Blagojevich maintains that, on average, the drugs from these countries are 25–50% less expensive than in the United States and identical to the FDA-approved counterpart in every respect other than price.[98]

Despite the purported savings the program offers, its aggregate impact has been minimal. Pharmaceutical companies have sought to obstruct foreign pharmacies selling to Americans by tightening oversight over their wholesale distribution[99] and the FDA has targeted shipments into the United States by I-Save RX.[100] Moreover, with 27 million eligible residents to the program, fewer than 20,000 orders were placed in its first two years of operation. Perhaps its most important (and intended) function is as a "political symbol."[101]

V. Conclusion

Despite the re-importation-friendly political environment that has likely emerged from the presidential and congressional elections, the possibility of a relaxation of restrictions on drug importation and re-importation is uncertain. As a U.S. Senator, President Barack Obama voted in favor of legislation that would permit drug re-importation.[102] The Senate and House of Representatives are currently in the hands of Democrats, who have been generally more receptive to re-importation than Republicans. Further, the recent credit crisis engulfing the global economy, if it precipitates a sustained economic decline, may pressure Congress to take actions to lower the cost of healthcare by passing re-importation legislation. Legislation enabling re-importation is already awaiting action in Congress.[103]

Yet recent events remind us of the added health risks associated with the manufacturing of drugs and other FDA regulated products that are not under the constant regulatory watch of the FDA. The deaths caused by Heparin manufactured in a Chinese facility[104] and the warning letters[105] and import alert[106] issued by the FDA to the largest foreign supplier of generic drugs to the United States, Ranbaxy Laboratories Ltd., for deviations from GMP in two of their facilities in India,[107] eroded the public's support for re-importation. Advisors for President Obama express that the Heparin incident will make it more challenging to pass reimporation legislation.[108] Lastly, the influence of the pharmaceutical industry can never be underestimated. With billions of dollars at stake, American pharmaceutical companies will continue their vigorous lobbying efforts. It is thus uncertain whether the "invisible hand" will provide Americans with cheaper drugs anytime soon.

1 *Vermont State v. Leavitt*, 405 F. Supp. 2d 466, 469 (D. Vt. 2005) (explaining facts of case).
2 *See* Melicia Seay, *Drug Importation*, Health Policy Tracking Service (Thomson West) ¶ 3 (July 10, 2006), *available at* http://www.netscan.com/EG-NSCNFS-B02/HPTSFILES%5CISSUEBRIEFS% 5CDrug1460.pdf.
3 *See infra* Part IV(B)(ii).
4 Colleen Newvine, *Conference explores pros and cons of drug reimportation*, University of Michigan News Service, Nov. 3 2003, *available at* http:// www.umich.edu/~urecord/0304/Nov03_03/07.shtml.
5 *See infra* Part IV(B).
6 *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescripton Drug Markets*, 5 Yale J. Health Pol'y L. & Ethics 193, 288 (2005).
7 *See* Devin Taylor, Note, *Importing a Headache for Which There's No Medicine: Why Drug Re-importation Should and Will Fail*, 15 J.L. & Pol'y 1421, 1434 (2007).
8 *See id.* at 1434-35.
9 Jared Martin, Note, *United States Prescription Drug Crisis: Reimportation of Canadian Prescription Drugs Is Not the Answer*, 27 J. Legal Med. 477, 478-79 (2006).
10 Taylor, *supra* note 7, at 1435.
11 Seay, *supra* note 2, at ¶ 3.
12 Martin, *supra* note 9, at 479.
13 Matthew Bishop, *Price Discrimination* adapted from *Essential Economics* (Profile Books), *available at* http://www.economist.com/research/economics/searchActionTerms.cfm?query=price+discrimination.
14 *Id.*
15 Martin, *supra* note 9, at 479.
16 21 U.S.C §§ 301-399 (2008); Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, Food and Drug Law: Cases and Materials 13 (3rd ed. 2007).
17 *See* Hutt, Merrill & Lewis, *supra* note 16, at 14-15
18 *Id*. at 15.
19 *See id.* at 13.
20 *See id.* at 14
21 *See id.*
22 *See id.*
23 *See* Matthew B. Van Hook, *Securing the Global Supply Chain: Evolving Federal/State Law – Prescription Drug Distribution, Counterfeit, Pedigree Requirements, and the Internet, in* Patents Copyrights, Trademarks, and Literary Property Course Handbook Series 917-18 (Practicing Law Institute 2006).
24 *See id.* at 918.
25 21 U.S.C § 351(a) (2008).
26 *See Leavitt*, 405 F. Supp. 2d at 473.
27 21 U.S.C. § 331 (2008); Van Hook, *supra* note 23, at 918.
28 *Leavitt*, 405 F. Supp. 2d at 473; see 21 U.S.C. §§ 331(a), (d) (2008).
29 21 C.F.R §201.100(a)(1)(i) (2009).
30 *See* Van Hook, *supra* note 23, at 919.
31 A pedigree is a "statement . . . identifying each prior sale, purchase, or trade of such drug (including the date of transaction and the names and addresses of all parties to the transaction), *Id*. at 915 (citing 21 U.S.C. § 353(e)(1)(A) (2008)).
32 *See id.* at 919.
33 *See generally* Part II.A.i.
34 Food and Drug Administration, FDA and the Drug Development Process: How the Agency Ensures That Drugs are Safe and Effective (2002), *available at* http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.pdf.
35 *See id.*
36 *See id.*
37 *See id.*
38 *See* Food and Drug Administration Center for Drug Evaluation and Research, New Drug Application (NDA) Process, http://www.fda.gov/cder/regulatory/applications/nda.htm (last visited Feb. 9, 2009).
39 *See id.*
40 Food and Drug Administration Center for Drug Evaluation and Research, Generic Drugs: Questions and Answers, http://www.fda.gov/cder/consumerinfo/generics_q&a.htm#whatare (last visited Feb. 9, 2009) (explaining distinctions between generic and brand-name drugs).
41 Food and Drug Administration Center for Drug Evaluation and Research, Abbreviated New Drug Application (ANDA) Process for Generic Drugs, http://www.fda.gov/cder/regulatory/applications/ANDA.htm (last visited Feb. 9, 2009).
42 *See* 21 U.S.C. § 381(a) (2008).

43 Christine M. Humphrey, Note, *The Food and Drug Administration's Import Alerts Appear to be "Misbranded"*, 58 Food & Drug L.J. 595, 597 (2003).
44 *See id.* at 597.
45 *See id.* at 597-98; *see also* 21 U.S.C. § 381(a) ("If it appears from the examination or otherwise…).
46 *See* 21 U.S.C. § 381(a).
47 *See* Food and Drug Administration, Office of Regulatory Affairs, Regulatory Procedures Manual, Ch. 9-6 "Detention without Physical Examination (DWPE)," *available at* http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-6.html.
48 *See* Humphrey *supra* note 43 at 595.
49 *See Sugarman v. Forbragd*, 405 F.2d 1189, 1190 (9th Cir. 1968) (involving an action to review FDA refusal to admit coffee beans offered for import).
50 21 C.F.R. § 1.94(a) (2008).
51 *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967).
52 American-manufactured drugs that comply with FDA standards, but that cannot be imported because of the express ban on reimportation and foreign drugs manufactured abroad, will be referred to collectively as unapproved unless referred to individually.
53 Dep't of Health & Human Servs., Task Force on Drug Importation, Report on Prescription Drug Importation ix (2004), *available at* http://archive.hhs.gov/importtaskforce/Report1220.pdf.
54 *See infra* Part IV(B).
55 *See e.g.,* Katie Merx, *Canadian Drugs Beat Medicare, Many Say*, Detroit Free Press, Apr. 6, 2006, *available at* http://www.redorbit.com/news/health/460473/canadian_drugs_beat_medicare_many_say_seniors_us_plan_not/index.html.
56 Food and Drug Administration, Office of Regulatory Affairs, Regulatory Procedures Manual, Ch. 9-2 "Coverage of Personal Importation," *available at* http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-2.html [hereinafter *Manual*]; *see* Terry, Prescriptions sans Frontières, *supra* note 59, at 272 n. 129 (characterizing the enforcement guidelines found in the manual as a de facto exemption for personal importation from the general prohibition on drug importation and re-importation).
57 Department of Homeland Security Appropriations Act of 2007, Pub. L. No. 109-295 § 535 (2008).
58 Nicolas P. Terry, *Prescriptions Sans Frontieres (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)*, 4 Yale Pol'y L. & Ethics 183, 203-4 (2004).
59 Terry, Prescriptions sans Frontières, *supra* note 56, at 205 (citing 21 U.S.C. § 956(a) (2008)). 21 U.S.C. § 956(a) (2008).
60 *Id*. § 956(a)(2); see Terry *supra* note 56 at 204.
61 *Manual*, *supra* note 56.
62 *Id*.
63 *Id*. (emphasis added).
64 *Id*.
65 *Id. see* Terry, Prescriptions sans Frontières, *supra* note 56, at 272 n. 129 (characterizing the enforcement guidelines found in the manual as a de facto exemption for personal importation from the general prohibition on drug importation and re-importation).
66 Van Hook, *supra* note 23, at 921.
67 Department of Homeland Security Appropriations Act of 2008, § 535 (emphasis added).
68 *Id*. (emphasis added).
69 21 U.S.C. § 381(d)(2).
70 Pub. L. No. 108-173, 117 Stat. 2066.
71 Pub. L. No. 100-293, 102 Stat. 95.
72 21 U.S.C. § 381(d)(1) ("Except as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.")
73 Van Hook, *supra* note 23, at 914.
74 *Id*. (quoting) (*Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong., 2nd Sess., p. 20 (Comm. Print 99-Z 1986) (Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Hon. John D. Dingell, Chairman)).
75 *Id*.
76 Martin, *supra* note 9, at 484.
77 *Id*. at 483
78 *See* Martin, *supra* note 9, at 484.
79 *Id.*
80 21 U.S.C. § 384(b) (2008).
81 *Id*. § 384(j)(2).
82 *Id*. § 384(1)(1).
83 *Montgomery County, Md. v. Leavitt*, 445 F. Supp. 2d 505, 510 (S. Div. Md. 2006).
84 *Id*.
85 *Vermont*, 405 F. Supp. 2d at 469-70.
86 *Id*. at 471.
87 *State v. Leavitt*, 405 F. Supp. 2d 466 (D. Vt. 2005).
88 *Id*. at 470.
89 *Id*. at 474 ("Vermont relies on a highly implausible interpretation of the statute.").
90 *Id*. at 475.
91 *Id*. at 474.
92 *See* 21 U.S.C. § 331 ("The following acts and the causing thereof are prohibited:").
93 *Leavitt*, 445 F. Supp. 2d at 507.
94 *See id.* at 516.
95 Nicolas P. Terry, *Under-Regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. New Eng. L. Rev. 421, 450 (2007) [hereinafter *Medical Tourism and Outsourcing*].
96 *Id*. at 450.
97 *Id*.
98 *See* Martin *supra* note 9, at 486.
99 *See, e.g.,* Bernard Simon, *Pfizer Moves To Try To Stop Drugs from Canada*, N.Y. Times, Jan. 14, 2004, at W1, *available at* 2004 WLNR 5507399 (Westlaw); Fearing End to Canada Drugs, States Now Look to Europe, USA Today, Jan. 14, 2005, *available at* http://www.usatoday.com/news/health/2005-01-14-drugs-europe_x.htm.
100 FDA: Seizes Shipments Imported Through I-Save Rx Program, Am. Health Line, Mar. 10, 2005, *available at* http://www.lexisnexis.com/lawschool/research/default.aspx?ORIGINATION_CODE=00092&signoff=off.
101 *Medical Tourism and Outsourcing*, *supra* note 102, at 451.
102 *See generally Jeffrey Young*, Biotech industry not seeing much difference between McCain, Obama. The Hill, Sept. 8, 2008 *available at* http://thehill.com/business--lobby/biotech-industry-not-seeing-much-difference-between-mccain-obama-2008-09-08_2.html.
103 *See* Pharmacuetical Market Access and Drug Safety Act of 2007 S.242, 110th Cong. (2007) ; *See* Drug and Device Accountability Act of 2008 S.3409, 110th Cong (2008).
104 *McCain and Obama Rethink Drug Importation. Legal Broadcast Network.*, Oct. 1, 2008. *Available at* http://blog.legalbroadcastnetwork.com/the-lbn-blog/2008/10/1/mccain-and-obama-rethink-drug-importation.html.
105 *See* 21 C.F.R. § 100.2 (2008) ("Informal enforcement actions include warning letters . . . .").
106 *See supra* Part III.a.ii.
107 *FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India*. U.S. Food and Drug Administration. Sept. 16, 2008, *available at* http://www.fda.gov/bbs/topics/NEWS/2008/NEW01886.html.
108 *McCain and Obama Rethink Drug Importation. Legal Broadcast Network.*, Oct. 1, 2008. *Available at* http://blog.legalbroadcastnetwork.com/the-lbn-blog/2008/10/1/mccain-and-obama-rethink-drug-importation.html.

Will the Health Sector Withstand Tough Economic Conditions?

Kimberly Hodgman

With growing anxiety over unemployment rates, lawmakers and job seekers hunt for industries that promise both growth and job security. The health care sector ranks high as one of the most secure industries.

Seeming resilient to the downturns of the economy, the Bureau of Labor predicts that the health care sector will add 3 million jobs between 2006 and 2016 despite the monumental job cuts in other sectors. For decades, the job pool could not keep up with the demand and hospitals even searched outside the United States to fill positions.

With statistics like these, it is no wonder that President Barack Obama has targeted the health sector for investment in both job training and job creation. On February 19, 2009, President Obama signed the *American Recovery and Reinvestment Act of 2009* (H.R. 1) dedicating $59 billion for investment in the health care sector. The bill specifically marked $500 million for the training and education of health care professionals to alleviate shortages.

Still, it is not all sunshine and rainbows for the health care industry. With a rise in unemployment, doctors are treating more uninsured patients. Likewise, the declining stock market has yielded lower dividends for hospital investments. Furthermore, patients are declining to proceed with elective surgeries. These three factors have contributed to lower fiscal performance of some hospitals leading to cutbacks and hiring freezes.

Individuals hoping to grab one of the coveted health care jobs should expect more competition in the future. Federally funded access to training will contribute to a larger applicant pool. With the uncertainty of the economy many current employees are reluctant to leave their positions, resulting in decreased attrition and lower demand for employment.

The Economic Crisis' Effect on Obesity

Kristen Barry

The Federal Centers for Disease Control and Prevention recently reported that while a third of Americans are obese, this number has shown signs of stabilization. The downturn in the economy has lead many researchers to fear that this number will begin to rise as American's put on what has been referred to as "recession pounds."

In the current economic climate individuals have cut back on the amount they spend on food. Cutting back on the cost of groceries often means cutting back on the quality of food. Fresh fish, fruits, vegetables, and whole grains can cost a person up to three times the amount they would spend on the caloric equivalent processed foods, high in fat and sugars.

In addition to a healthy diet, a person needs to exercise to prevent obesity. The cost of joining a health club or athletic group is money that many Americans no longer have or can justify spending when they are unsure of when their next paycheck will come. The emotional and physical stress that economic uncertainty causes may prevent people from exercising, leaving them with no energy to maintain a nutritious diet.

During late 2008, when most stocks were crashing, stocks of fast food companies were outperforming predictions. McDonald's reported increased sales globally in the third quarter of 2008, while the organic grocery store Whole Foods had a substantially lower sales increase than in 2007. Amidst all the dark predictions of obesity during the economic crisis, some experts suggest that this is an opportunity for Americans to revamp their unhealthy eating habits by consuming less and cooking at home.

The Suleman Octuplets: Raises Questions about the Need for Responsible Reproduction

Megan McCarthy

With the power and ability to manipulate reproduction comes responsibility and accountability on the part of patients and doctors. On January 26, 2009, Nadya Suleman gave birth to octuplets, resulting in only the second set of octuplets born in the United States. After the news of this medical wonder was released, several startling facts about Ms. Suleman came to light. When 33-year-old Suleman was implanted with six embryos through in vitro fertilization that resulted in her octuplets, she already had six children ranging in age from two to seven, no clear source of income, no husband, no home of her own, and was receiving government assistance. Suleman lives with her mother in a home that has gone into mortgage default, three of her older six children are receiving disability benefits, and the family receives $490 each month in food stamps.

Suleman's case raises questions about the lack of regulation covering doctors and clinics that provide fertility services. Giving birth to extreme multiples comes with tremendous risks for both the mother and the babies. Multiple-birth pregnancies place a mother at high risk for premature labor and delivery, and they put the babies at an increased risk for brain injuries, underdeveloped lungs and intestines, cerebral palsy, and several other lifelong medical and developmental disabilities. Medical guidelines provide that women under the age of 35 should not be implanted with more than two embryos "in the absence of extraordinary circumstances." Even though these guidelines state that implanting more than 2–3 embryos is risky and outside the scope of acceptable medical practice, Suleman was implanted with six.

While organizations like the American Society for Assisted Reproductive Medicine and the Society for Assisted Reproductive Technology provide guidelines for fertility doctors to follow, these guidelines are not legally enforceable. Suleman's case raises the question of whether physicians should screen their patients and take into account whether prospective mothers or couples may have any feasible means of supporting their children. A basic consideration of whether the parents can financially support their children is one factor that could be a minimum requirement for fertility treatments, though implementation of this policy is likely to face great opposition.

Recent Statistics on HIV/AIDS in the District of Columbia Show that it is a City-Wide Epidemic

Molly Conway

In February 2009, the District of Columbia ("the District") Department of Health released the 2008 HIV/AIDS epidemiology update report. This report found that three percent (n=13,466) of the District's residents are known to currently live with HIV/AIDS – a figure that is 22% higher than in 2006. Comparatively speaking, the U.S. Centers for Disease Control and Prevention (CDC) define an HIV/AIDS epidemic as severe when it exceeds one percent of the residents in a given geographic area. This figure is higher than in West Africa and is similar to Kenya and Uganda. It is expected that the number of afflicted individuals is between one-third and one-half higher because many individuals are not aware of their status.

The gender and race combination with the highest rate of HIV/AIDS is African American males; the age group with the highest rate of the virus is 40-49 – both groups are around seven percent. About three percent of African American women and Caucasian men, respectively, currently live with HIV/AIDS. The lowest rate of HIV/AIDS is in Caucasian women who are at two-tenths of a percent. The transmission of HIV/AIDS occurred most often in male homosexual relationships, heterosexual relationships, and intravenous drug use.

The District is divided into eight wards. Each ward averages around two percent of their respective population living with the virus (although twenty percent of individuals who tested positive did not record the ward in which they reside), with the exception of Ward 3 – notoriously the wealthiest ward in the District. Of the over 13,000 individuals living with HIV/AIDS, about 1,200 are homeless (n=401) or incarcerated (n=891), as of the time of testing.

A brief glimpse at the correlation between socioeconomic status and HIV/AIDS is seen from the ward statistics. In 2009, the District will perform more targeted studies to determine which subgroups are most afflicted. It is apparent, however, that this is a city-wide epidemic, one that cannot attributed solely to an individual's socioeconomic or racial background.

Washington Update: The Economic Recession and the Government's Response

Health Information Technology in the *American Recovery and Reinvestment Act of 2009*

Molly Conway

Health Information Technology ("Health IT") is the electronic compilation of medical records to create a comprehensive management system of individuals' health information. The *American Recovery and Reinvestment Act of 2009* (H.R. 1) allots more than $19 billion for the creation of a national central Health IT system. This legislation will provide incentives to medical institutions and physicians who currently utilize electronic medical records ("EMRs") and those who decide to follow suit. Additionally, funds are provided for Indian Health Services to further telehealth initiatives and provide physicians access to state-of-the-art procedures. This package also creates a pool of money for grants to physicians and training institutions and allocates funds for infrastructure needed to further the use of Health IT. Finally, a significant portion of the Health IT funding is set aside for Medicare and Medicaid.

Currently, an individual who has several doctors may unnecessarily undergo the same test for each doctor. With EMR, the results can be disseminated to all doctors who request the same test so as to save the patient time and money. It is expected that the utilization of EMR in Medicare and Medicaid will save more than $12 billion over the next decade.

Most notably, the legislation creates the Office of the National Coordinator for Health Information Technology within the Department of Health and Human Services. This Office will ensure security of information while implementing a central entity to review policies and recommend changes for a seamless process.

It is expected that in the next decade, 70% percent of hospitals and 90% of physicians will utilize electronic health records. The advent of a national Health IT program is only the first step in health care cost savings and will ensure that individuals receive the best care possible.

The *American Recovery and Reinvestment Act* Impacts COBRA Benefits

Kathryn Coniglio

With the number of unemployed workers in the United States reaching record highs, new policies are being implemented to accommodate the healthcare needs of the newly jobless. Since 1985, the Consolidated Omnibus Budget Reconciliation Act (COBRA) has allowed employees who have lost their jobs to maintain healthcare benefits for eighteen months, as long as they had coverage

prior to being laid off and were not terminated for misconduct.

The American Recovery and Reinvestment Act, signed into law February 17, 2009, has greatly affected the COBRA program. The Act contains a number of COBRA revisions, effective immediately. Previously, employees paid COBRA premiums out-of-pocket. Under the new law, the government will subsidize 65% of costs. Employers will be required to pay the subsidized portion directly to the government and will be reimbursed through reduced remittance of payroll taxes withheld from employees.

Anyone laid-off on or after September 1, 2008 will have 60 days to retroactively enroll in COBRA at 35% of the original cost. Employers must notify terminated employees of a "second chance" at this health care coverage. Reduced premiums will be available for those laid off through December 31, 2009. COBRA benefits will last for nine months, until the individual becomes eligible for another health plan, until the 18-month coverage period expires, or until the individual fails to contribute his 35% share, whichever date comes first. Those individuals who choose to utilize subsidized COBRA benefits will not face increased income taxes unless the individual falls into a high-income bracket.

Healthcare experts have already voiced concerns that the expansion of COBRA will discourage employers from offering health insurance. Although employer contributions will be reimbursed quarterly, companies already strained by the economic downturn may choose to eliminate healthcare benefits rather than "loan" the government COBRA payments for each laid off employee who elects coverage.

An Overview of Health Sector Spending in President Obama's Stimulus Package

Walakewon Blegay

Within the first 100 days of his presidency, President Barack Obama's "American Recovery and Reinvestment Act of 2009 (ARRA)," a $787 billion economic stimulus package, passed both Houses of Congress and was signed into law. ARRA has a number of provisions directed towards changes in the healthcare system, funneling approximately $150 billion to a number of major health care initiatives. States will receive an additional $87 billion of matching funds to bolster their Medicaid programs over a 27-month period.

Additionally, the National Institute of Health (NIH) will receive $10 billion for research grants in areas such as cancer, Alzheimer's disease, heart disease, stem cells, and for renovation of research facilities. The Department of Veterans Affairs will receive $1.2 billion to construct and renovate healthcare facilities and national cemeteries. The package allocates the Department of Defense $2.3 billion to fund construction of military health and dental clinics. ARRA will distribute $1.1 billion between the Agency for Healthcare Research and Quality, NIH, and the Department of Health and Human Services to compare the effectiveness of medications and medical devices. In addition, prevention and wellness programs will receive $1 billion to address the issues of obesity, smoking, and other risk factors for chronic disease and immunization.

President Obama noted that an estimated 45.7 million Americans are uninsured, and pledged that ARRA was the first step to insulating Americans from what he called "the crushing cost of health care."

WCL Health Law Project Announces

Health Law and Policy Institute: June 15–19, 2009

With pleasure, the Health Law Project, Program on Law and Government announces the second annual Health Law and Policy Institute. This one-week program, which will be held from June 15–19, 2009, will provide J.D. and LL.M. students and practitioners with intensive training in a broad spectrum of health law and policy topics.

The Summer Session Health Law and Policy Institute is designed for legal professionals who are practicing or preparing to practice health care law, and offers training in theoretical and practical aspects of health law and policy. American University Washington College of Law's location in the nation's capital also provides students with an opportunity to combine participation in the Institute with exciting externships or summer positions that will enrich their health care law experience.

*Courses may be taken for academic credit or for Continuing Legal Education. These credits can also be applied toward an LL.M. degree with a Health Law specialization in the Law and Government Program. A Certificate of Attendance will be presented to participants who do not wish to receive academic credit. Course schedule and offerings are subject to change. International Participants should apply at least five weeks in advance and bear the sole responsibility for applying for and obtaining a visa at the American Embassy or Consulate in their country. Applicants whose first language is not English must submit a minimum TOEFL score of 580 or a written certificate of proficiency from an accredited language institution, unless applicant holds a degree from an accredited U.S. institution. Completed application and a $65 non-refundable application fee should be mailed directly to the Registrar's Office.

Registration Information:

2009 Calendar

Completed Application and Fee Due: **May 2**
Registration ends: **May 15**
Classes begin: **June 15**
Classes end: **June 19**
Take-home exams/papers**: **July 12**
**if applying for academic credit

Tuition and Fees for Students

Tuition per credit for 2009: **$1431**
Non-refundable Application Fee: **$65**
Student Activity Fee: **$50**
Note: Tuition does not include expenses for books and other reading materials.

To inquire more about the program, receive an official brochure, or request an application, please contact:

Summer Session Health Law and Policy Institute
American University Washington College of Law
4801 Massachusetts Avenue, NW
Washington, DC 20016
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Summer Session Program

Courses

Introduction to International Health, Human Rights, and Public Health

Introduces students to the substance and theory of human rights law through a focus on public health. Exploring the linkage between human rights, international public health policy, and international law, the course examines the right to health vis-à-vis other human rights, as framed by international treaties and covenants.

Introduction to Medicine for Lawyers

Teaches up-to-date information in an introduction to basic medical principles and practices, and reviews medical negligence law for those students interested in medical liability issues.

Intersection of Intellectual Property and Health Care

Provides significant exposure to the many relationships between U.S. patent, trademark, and copyright laws and health care, including access to medicines, data privacy, genetics, and biotechnology.

Legal Issues in Health Care Fraud and Abuse

Examines fraud and abuse in the delivery of health care through discussions of the criminal and civil laws and regulations that combat various forms of health care fraud. Course includes a False Claims "Boot Camp," as well as Stark and Anti-kickback statute issues, health care anti-fraud enforcement efforts, sanctions, and compliance.

Introduction to Health Care and Life Sciences Fundamentals

Addresses the unique issues attorneys face in counseling health industry clients, including coding, coverage, reimbursement, billing, compliance, and other regulatory matters. Includes Congressional and state legislative initiatives, and recent federal government regulatory actions.

Introduction to Bioethics

Considers legal, ethical, and public policy problems posed by developments in health care financing, allocation, and delivery. Topics include bioethics, federal reform of health policy, health care dispute resolution, health care transactions, managed care, medical liability, health law legislative and regulatory process, and public health law.

Introduction to Genetics

Introduces students to the many ways in which the legal system, construed broadly, is influenced by and influences the science of genetics. This course also aims to introduce students to the ethical and societal concerns raised by new genetic technologies and how the law addresses these issues or may do so in the future.

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