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Is the U.S. Public Health System Ready for Bioterrorism? An Assessment of the U.S. Public Health Infrastructure and its Capacity for Infectious Disease Surveillance

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Bioterrorism has become a household word. For years experts have warned of the potential of bioterrorist events, and today we have finally experienced the reality of this particular horror. As the nation garners resources to combat current and future bioterrorist activity, questions and debate arise as to the appropriate allocation of resources. Most funding appears targeted toward vaccines and medical supplies with little focus on the underlying public health infrastructure. However, it is the infrastructure-the organizations and people who comprise the nation's public health system-that will ultimately determine the success of any efforts to fight the spread of infectious diseases, including those resulting from bioterrorism. Within the overarching infrastructure, it is the nation's capacity to conduct infectious disease surveillance-detecting unusual disease patterns, investigating sources of outbreaks, and triggering control efforts-that will play the greatest role in our success or failure in combating infectious diseases.

In light of ongoing concerns about the nation's public health infrastructure and infectious disease surveillance capacity, we undertook a study to identify gaps in the system and specific areas in need of improvement. We performed this study on behalf of the Assistant Secretary for Planning and Evaluation in the Department of Health and Human

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Services. Given recent events, we believe it is important not only to present the gaps in the system as identified by our study, but also to provide readers with a context and framework for discussing surveillance activities. This Commentary presents a discussion of the goals of infectious disease surveillance, a framework for understanding and discussing the U.S. public health infrastructure in which surveillance occurs, and the results of our analysis on gaps in the infectious disease surveillance system.

I. BACKGROUND

Infectious diseases are the leading cause of death worldwide, and the third leading cause of death in the United States. In the twentieth century therapeutic advances, such as the introduction of antibiotics and the development of vaccines, have decreased the risks posed by infectious diseases. Dramatic medical successes led some experts in the 1960s and 1970s to proclaim that infections had been conquered in this country and were no longer a significant hazard. However, in the last twenty years, infectious diseases have once again become a threat.

A. Increasing Threat of Infectious Diseases

As we move into the twenty-first century, biological, sociological, technological, and political factors have converged to promote the emergence of new infections, and renew anxiety about the possibility of bioterrorism and the resurgence of some conditions that were thought to have been conquered only a few decades ago.

Globalization of the world economy has increased the reach of pathogens. Rapid air travel allows a person who has early, minor, or misleading symptoms of a dangerous, highly contagious infection to expose hundreds of others in planes, in airports, and in hotels around the world. International businesses and rapid transportation create the possibility that food can be contaminated in one country, further contaminate large quantities of food in bulk processing plants in another country, and be shipped to yet additional countries where illness results.

Bioterrorism is also an increasing concern. Large quantities of highly communicable microorganisms can be grown inexpensively, transported inconspicuously, and released anonymously by terrorists to produce widespread panic, illness, and death.

Other infectious disease challenges are more subtle but represent an equal if not greater threat to the health of the public. Decades of use and misuse of antimicrobial agents are inducing antibiotic resistance in organisms once readily treated. Most physicians have limited clinical experience with many significant infectious disease threats, and a large portion of the public have been protected from epidemic and endemic infections that were part of the day-to-day reality for their parents and grandparents. As a result, the public's responses to infectious disease threats are muted.

B. Role of Surveillance in Detecting Infectious Diseases

Surveillance is widely regarded as the key to detecting new and emerging diseases, as well as tracking incidence and prevalence of established diseases. Surveillance data help detect unusual disease patterns and trigger control efforts. In 1963, Alexander Langmuir, organizer of the Epidemic Intelligence Service (EIS) at the Centers for Disease Control (CDC), coined the modern definition of public health surveillance, which was later endorsed by the World Health Organization (WHO). Langmuir defined public health surveillance as having three elements: (1) the systematic *collection* of pertinent data; (2) the orderly *consolidation* and *evaluation* of the data; and (3) the prompt *dissemination* of results to those who need to know (e.g., relevant health authorities).

The data referred to in the above definition include information such as the diagnosis of the disease, disease severity, geographic distribution of cases, and the route of transmission. The unit of analysis in surveillance is a *case*, which is an instance of a single individual with the disease.

The definition implies an ordered sequence of discrete activities or events that can be used both for circumscribing the surveillance process and for assessing what needs to be improved. Essential steps in the surveillance process include: (1) diagnosis of a health event by clinicians and laboratories; (2) reporting of health events and other disease information to local, state, and/or federal health agencies (reporting sources include clinicians, laboratories, hospitals, schools, and vital statistics records); and (3) management of health event data. Once information is reported, the data are collected, entered into a data management system, and edited. The information is then analyzed to establish baseline disease information and time trends. The data are examined for the identification and documentation of outbreaks. Reports are then generated and disseminated so that appropriate public health actions can be taken.

Surveillance activities can recognize the occurrence of new or emerging infections and track the prevalence of infectious agents already established in human populations. Effective surveillance programs are able to detect unusual clusters of disease, document the geographic and demographic spread of an outbreak, and estimate the magnitude of an

infectious disease problem. In addition, effective surveillance helps identify the natural history of a disease and factors responsible for its emergence, facilitates laboratory and epidemiological research, and assesses the success of specific intervention efforts.

Poor surveillance leads to incomplete, non-representative, and untimely disease reporting. These gaps leave policy makers and medical personnel without a basis for setting policy to control the spread of infectious diseases and to mount an effective prevention and treatment campaign. For example, in the 1980s tuberculosis was no longer considered a significant problem, and surveillance of the disease declined. The reemergence of the disease in the early 1990s, particularly multi-drugresistant strains, took the public health and medical communities by surprise.

C. Surveillance Challenges

Changes in the systems to provide and pay for health care pose both an opportunity and a threat to surveillance of infectious diseases. Concerns over double-digit health care inflation in the 1980s made cost control a number one priority for both policy makers and the major payers for health care delivery, private employers. During the past two decades the U.S. population has rapidly moved into managed care. The promised focus of managed care—managing the health of a population—should bring the goals of the delivery system closer to those of public health. There is great potential for productive collaboration in prevention of illness and in using managed care databases to integrate patient data across the continuum of care.

On the other hand, concerns about costs have changed clinical and laboratory practices in ways that limit the availability and reduce the utility of information upon which infectious disease surveillance has traditionally been based. Intense competition and razor-thin profit margins among laboratories have driven the adoption of highly efficient processes that narrow the range of tests conducted on specimens. New technologies allow private labs to identify the nature of an individual patient's illness faster and cheaper so that growth and identification of the specific pathogen are sometimes not needed to recommend appropriate treatment. While this represents an advantage to efficiency and effectiveness of care for the individual patient, it obviates the clinical need for tests of public health significance.

Current capacity for infectious disease surveillance is a product of a century of piecemeal investments as the country has organized to respond to various biological threats. Much of the investment has been categorical, resulting in uneven capacity depending on disease type and fragmentation of surveillance efforts across the spectrum of infectious disease threats. The CDC alone has literally hundreds of data collection systems and data sets.

Legal authority for surveillance rests with the states and localities, adding another dimension to the fragmentation noted above—not only is surveillance fragmented by disease type, it is also fragmented geographically. The presence of hundreds of jurisdictions makes it difficult and confusing for those required to report infectious diseases and can make it hard to identify and respond to threats that cross county and state boundaries. The lack of standards for data collection, storage, and transmission makes it hard for states and localities to work collaboratively to develop more effective interfaces with the private sector.

Differing authority and oversight also mean different levels of resources devoted to surveillance at both the state and local level. There is currently a lack of consensus or guidelines for what should be monitored, by whom, and in which populations. As such, capabilities vary substantially both within and across states. Despite expanding expectations for the scope and nature of surveillance efforts, resources devoted to surveillance have changed little at the local level, and in many places have actually declined.

Thus, as the threats of infectious diseases increase, it becomes crucial to re-examine the public health system in this country. Preparing a defense against bioterrorism, as well as naturally occurring infections, will require targeted interventions to ensure the presence of a strong and reliable public health infrastructure and surveillance system.

II. METHODOLOGY

This study was based on an analysis of recent literature,¹ interviews with fifty-five surveillance experts in the field, and validation through direct observation of the capacity currently in place for surveillance in Baltimore, Oregon, and West Virginia.² Additionally, we received input from a blue ribbon panel drawn from state and local health departments, academe, private provider systems, laboratories, and the CDC. This study was conducted in 1999 and 2000, but given the tenacity and systemic nature of the issues identified by our study, we consider our results to remain highly relevant today.

We thoroughly reviewed the literature pertaining to infectious disease surveillance. This enabled us to synthesize current thinking on the topic and to pinpoint specific issues or gaps within the public health infrastructure and surveillance activities for which there is widespread

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concern among published authors and researchers. The key issues identified through the literature review formed the basis of our subsequent interviews with surveillance experts.

After completing the literature review, we conducted detailed conversations with fifty-five surveillance experts around the country and in Canada. These surveillance experts represented local and state governments, the CDC, academic institutions, laboratories, private providers, managed care organizations, the military, and the Veterans Administration.

Using the literature review results as a starting point, we developed a conversation guide to structure our discussions.³ As part of the interviews, we provided each surveillance expert with one of seven surveillance scenarios (Appendix) and asked each person to describe: How the infectious disease surveillance process should work in dealing with this scenario? Where would it be likely to breakdown? Where would you invest resources to improve capabilities to handle this scenario? And what would you hope to achieve from this investment?

We also asked the surveillance experts to provide their definition of surveillance; describe surveillance successes and failures in which they were personally involved to illustrate the current strengths and weaknesses of surveillance capacity; discuss the strengths and limitations of surveillance with regard to selected issues including education and training, staffing, technology, information flow, legal authority, the impact of managed care, and other topics; and identify the types of situations that represent the greatest threat to the population's health.

The blue ribbon panel also met twice to provide input and guidance in this study. These meetings aimed to identify and prioritize opportunities to improve domestic surveillance of infectious diseases. In addition, for each opportunity area, the panel sought to identify minimal performance goals and objectives; to identify what core capacity needs to exist to meet these objectives; and to specify the interventions/investments that would be required to attain the core capacities and performance goals.

We also conducted a "goals and performance" exercise with the expert panelists. The exercise asked each panelist to rank the importance of eight goals of surveillance at each level of government on a five-point scale.⁴ It then asked each panelist to rank system performance relative to each goal at each level of government. The resulting data was displayed in a matrix format to visually depict gaps in the system.

Following the first blue ribbon panel meeting, we conducted site visits to test these identified gaps against the priorities of surveillance systems that have taken, or are currently undertaking, efforts to improve their surveillance capabilities. The site visits were conducted in January and February 2000.

III. RESULTS AND DISCUSSION

A. Goals of Infectious Disease Surveillance

Based on a review of relevant literature and the advice of the expert panel, we identified eight goals for infectious disease surveillance. These include:

1. Detecting Outbreaks of Infectious Diseases. Infectious disease surveillance allows public health officials to differentiate between endemic and epidemic levels of disease by placing current incidence statistics in the perspective of normal levels. An epidemic, or outbreak, of a disease is its occurrence at an unexpectedly high frequency. Determination of whether the level of disease is higher than normal is only possible when the "usual" or baseline rate of the disease is known. Surveillance systems regularly monitor the health status of populations and therefore allow the identification of baseline levels of different diseases. For instance, surveillance efforts have shown that the endemic level of measles in the United States is extremely low. Nearly all new outbreaks can be attributed to imported measles cases. This type of information helps policy makers focus disease control efforts.

2. Detecting Changes in the Epidemiology of Infection. Patterns of infection change over time. For instance, a disease that at one time primarily affected young children may now have its greatest effect on young adults or the elderly. Many factors can account for changes in the epidemiology of infection, such as implementation of a vaccination campaign or mutations in the infectious agent. For example, after vaccination for measles became routine in the United States, the average age at which individuals became infected rose significantly, changing the health care needs of the affected population. Surveillance identifies these important trends.

3. Providing Information to Prompt and Guide a Public Health Response at both the Individual and Population Level. Without a firm understanding of who, where, and why people become infected and by what, the public health community would have no reasonable approach for tackling a problem caused by an infectious agent. Surveillance was instituted to enable society to deal with immediate communicable disease threats. Surveillance information is critical for making intelligent decisions to protect the health of the public both at the population and the individual level. Botulism and meningitis surveillance both illustrate the multiple roles of surveillance information. The purposes of reporting suspected botulism are: (1) to aid clinicians in making the diagnosis of this rare disease; (2) to provide access to treatment, often available only through the public health service with the approval of state health officials; and (3) to identify the source of disease through a public health investigation. The source could be either a home-canned product, which generates one kind of public health response, or a commercial product, which generates a very different response. In the case of meningitis surveillance, the primary goal at the local level is to identify close family and child daycare contacts for prophylactic administration of rifampin within forty-eight hours to prevent other cases of disease.

4. Assessing the Health Status of the Public. A primary role of disease surveillance is the assessment of the overall health status of the public. Infectious disease surveillance provides descriptive information on the most frequent causes of morbidity and mortality in communities, the magnitude of health problems, and the demographic and geographic distribution of diseases.

5. Evaluating Prevention and Control Interventions. Prevention guidelines, screening, vaccination, efforts to change lifestyles, and other disease prevention and control interventions are designed to improve health outcomes. Surveillance systems enable the evaluation of these efforts by charting changes in health status before and after introduction of the intervention. For example, active surveillance of Group B Streptococcus, funded through the Emerging Infections Program, has monitored the burden of disease over time and has been crucial in measuring the uptake and impact of prevention measures. Likewise, the incidence of diseases for which vaccines are available can be used to assess the success of efforts to increase vaccination rates. Using surveillance data to evaluate prevention programs can improve program designs and better target public awareness campaigns.

6. Aiding in Understanding the Etiology and Natural History of Diseases. Disease surveillance data can be used to help understand the etiology (factors of causation) and natural history of diseases. Surveillance can provide information that helps determine the mode of disease transmission (e.g., vector-borne or water-borne); short- and long-term trends of disease (including the incidence, prevalence, and case fatality over time); risk factors for new and old diseases (e.g., age, gender, or comorbidities); and environmental factors related to diseases (e.g., warm climates or seasonal changes). However, undertaking surveillance exclusively for research purposes is uncommon since specific aspects of a disease are better investigated by more detailed data collection and tracking of cases (e.g., registries).

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7. Assisting in Health Planning. Information obtained from surveillance systems can be used to guide health planning. For example, health departments can use surveillance information to help prioritize efforts to combat the most prevalent preventable diseases, set target goals (e.g., Healthy People 2010), and estimate resource needs.

8. Identifying Research Needs. Disease surveillance can be used to identify gaps or unexplored areas of research. For example, surveillance data may reveal the emergence of a new antibiotic resistant strain of bacteria (e.g., penicillin-resistant strains of gonorrhea that required the development of new drugs for treatment). Additionally, surveillance may reveal that a certain disease has emerged in a previously unaffected population, thereby indicating the need for studies on possible reasons for this shift (e.g., socioeconomic changes or the influx of people from other communities).

B. Examining Surveillance Goals at Local, State, and CDC Levels

Meeting these goals requires collecting data, translating that data into information to support decision-making, and communicating that information to those who need to take action or be informed. Performance relative to these goals varies widely across jurisdictions. While all of these surveillance goals are important, the prioritization of these goals differs among various surveillance entities. In assessing areas in the public health infrastructure and surveillance system for improvement, it is critical to ensure that investments target high priority goals for which the current level of performance is inadequate.

Based on the assessment of the expert panelists, a number of goals fall into a "low performance/high priority" category. At the local level there are five such target goals including: detecting outbreaks, detecting changes in the epidemiology of infection, assessing the health status of the public, evaluating prevention and control interventions, and assisting in health planning (figure 1).

At the state level, the four goals that fall into the "low performance/high priority" category include: detecting changes in the epidemiology of infection, assessing the health status of the public, evaluating prevention and control interventions, and assisting in health planning (figure 2).

Finally, at the CDC level, only two goals fall into the "low performance/high priority" category: evaluating prevention and control interventions and assisting in health planning (figure 3).

In comparing the categorization of goals across the three levels of surveillance, the local level has the greatest number of target goals,

Figure 1. Goals of Surveillance—Performance and Priorities at the Local Level

- ✓1. Detecting outbreaks
- ✓ 2. Detecting changes in the epidemiology of infection
 - 3. Providing information to prompt and guide a public health response
- ✓4. Assessing the health status of the public
- ✓ 5. Evaluating prevention and control interventions
 - 6. Aiding in understanding the etiology and natural history of diseases
- ✓7. Assisting in health planning
 - 8. Identifying research needs
 ✓ = investment area



Figure 2. Goals of Surveillance-Performance and Priorities at the State Level

- 1. Detecting outbreaks
- Detecting changes in the epidemiology of infection
 - 3. Providing information to prompt and guide a public health response
- ✓4. Assessing the health status of the public
- ✓ 5. Evaluating prevention and control interventions
 - 6. Aiding in understanding the etiology and natural history of diseases
- Assisting in health planning
 - Identifying research needs
 ✓ = investment area



followed by the state level, with the CDC level having the best perceived performance overall. Thus, not only should an effective plan to improve the core capacity for infectious disease surveillance target specific surveillance goals that fall into the "low performance/high priority" category, but it should also focus resources on improving performance at the local level, either through direct investment in local capacity, or through federal and state support and the development of new data flow arrangements.

Figure 3. Goals of Surveillance—Performance and Priorities at the CDC Level



C. Framework for Assessing the Public Health Infrastructure and Infectious Disease Surveillance System

In accomplishing the goals described above, the core system for surveillance in this country involves a cascade of activities, with each step triggering a response from the next level of the system. As depicted in Figure 4, effective surveillance within the current hierarchical system requires a complex set of interactions and information flows among the clinical delivery system, public and private laboratories, and public health personnel at each level of government.

Laboratories and providers identify and report cases of infectious disease to the appropriate public health authorities. These data are used to guide an immediate public health response to individual reported cases of disease to (1)ensure correct diagnosis and treatment; (2) gather more detailed surveillance information such as risk factors; (3) identify, screen, and/or treat contacts who may also be at risk; and (4) appropriate public health response (e.g., determine the pulling contaminated food off the shelves). Moreover, public health officials translate these data into information to guide decision-making with respect to their broader role in protecting the public against infectious disease threats. These officials then provide data up the chain-local health officials provide data to state health officials who in turn provide data to the CDC. Each subsequent level of government conducts further analyses to understand the nature of biological threats and to develop strategies to address them. The information produced at each level in the system then

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ideally flows back down the chain to each of the entities involved in surveillance.

This core system is supported by educational institutions that train clinical and public health professionals, accrediting and licensing bodies that set standards, a public and private research establishment that provides supporting technologies, and policy makers who provide the funding and legal framework for surveillance of infectious diseases.



Figure 4. Interactions and Information Flows for Infectious Disease Surveillance

D. Critical Gaps in U.S. Infectious Disease Surveillance Capacity

Our analyses assessed ways to improve this intricately linked hierarchical system for surveillance of infectious diseases as well as ways to reorganize the system to take advantage of advances in communications technology, and to respond to infectious disease threats that increasingly cross county and state boundaries. Military surveillance systems and the United States' participation in global surveillance activities were beyond the scope of this project.

Below we identify a series of critical gaps that need to be addressed to ensure the population is adequately protected against infectious disease threats. We identified these gaps through the literature review and blue ribbon panel, and then validated them on the site visits.

1. Gaps in the Core Capacity of the Key Entities Involved in Conducting Surveillance of Infectious Diseases. This type of gap refers to the resources within state and local health departments, the CDC, public and private laboratories, and provider systems that allow each entity to perform its role in meeting the goals of surveillance. Our study identified the following specific gaps:

a. No clear standards exist that define the critical surveillance needs and associated capacity requirements at all levels of the system. While some efforts have been made to define standards for public health laboratories and food-borne diseases, no comprehensive and systematic effort has been undertaken.

b. Local capacity is not sufficient to ensure adequate performance across the eight goals of surveillance. Staffing, skill levels, technological capability, and training are uneven across the country, leaving some populations not as well protected from infectious disease threats as others. Local-level public health officials need support from state health departments and the CDC to develop needed skills, to back up local-level staff during outbreaks, and to provide technological support and guidelines for how to handle various situations. For example, after the report of a case, public health staff often have to contact the provider and/or the affected individual to obtain complete information about the clinical picture, demographics and risks, treatment options, and contacts who may be at risk and who may require testing or prophylactic treatment.

At one of the sites visited, a school bus driver was diagnosed with tuberculosis, requiring public health officials to identify and test more than one hundred children who may have been exposed. This investigative activity is a key, very labor intensive part of the surveillance process that often falls through the cracks because of a lack of local capacity. Without it, public health response to individual cases is difficult, and most case reports will be missing key information that make the data less useful for analysis at higher levels in the system.

c. Staff capacity at the state and large local level (cities and metropolitan areas) is frequently not adequate to support ongoing collection and analysis of surveillance data to detect changes in the epidemiology of infection, to evaluate surveillance efforts, to plan interventions, and to set priorities. For example, lack of staff capacity to conduct mosquito surveillance in New York City contributed to the delayed recognition of the West Nile Virus. Site visits confirmed reports that capacity varies widely both across states and localities, as well as across programs within a public health agency.

d. Computerized decision and analytic support tools have not been developed to their fullest potential to support infectious disease surveillance activities. For example, the military currently has the capability to collect patient data electronically on a real-time basis from field personnel. This data is fed into computer software that can detect when the occurrence of disease is outside its expected frequency. While this system is not currently applicable to public health on a broad scale, it illustrates the potential utility of electronic medical record data for surveillance within defined populations.

e. The public and private laboratory capacity supporting surveillance has eroded. Public health laboratories are perceived to be behind the private sector in terms of technology development, dissemination, and adoption. Meanwhile, private laboratories, which focus on clinical rather than broader public health needs, face cost pressures that have encouraged fewer and less specific tests. Private laboratory consolidation into large regional or national facilities has made the current practice of reporting separately to each jurisdiction cumbersome and impractical.

2. Gaps in the Flow of Data and Information Among the Entities Involved in Surveillance of Infectious Diseases. As outlined above, surveillance of infectious diseases involves a series of data and information flows among the numerous entities involved in surveillance. Our analysis identified a number of critical gaps in these flows (figure 5):

a. Provider and laboratory reporting of infectious diseases is incomplete and not timely. Case reporting is a critical foundation for infectious disease surveillance; full participation from the provider community is a necessary component of a functional surveillance system under current data flow arrangements. Estimates of completeness of reporting range from 6% to 90% for many of the common notifiable diseases. Reasons given by providers for not reporting include: assumed that the case would be

Figure 5. Gaps in Flows Among Entities



reported by someone else; unaware that disease reporting was required; do not have notifiable disease reporting form or telephone number; do not know how to report notifiable diseases; do not have the list of notifiable diseases; concerned about confidentiality; concerned about violation of doctor-patient relationship; reporting is too time-consuming; and absence of incentives to report.

b. A great deal of data flows through the system, but feedback and analyses need to be more effectively packaged and disseminated from the CDC to states and locals, from states to locals, and from public health venues to the clinical delivery system. Better feedback would help to engage the delivery system in infectious disease surveillance.

3. Gaps in the Structures that Support Surveillance. As described above, the core system is supported by educational institutions, accrediting and licensing agencies, the public and private research establishment, and policy makers. Figure 6 depicts gaps pertaining to these structures. Gaps identified with respect to these supporting structures include:

a. Public health workers specifically trained to do infectious disease surveillance are perceived to be in short supply.

b. Training programs do not adequately educate clinical health professionals on their role in surveillance.

c. Research and development of new laboratory technology is focused on clinical rather than public health applications. Advanced laboratory technology that is available to support surveillance needs to be disseminated and adopted more rapidly.

Medical/Nursing/ | Training Technology Other Professional Laboratories Providers **Training Venues** Research Venues Certification Boards Local Health Department Schools of 1 Haller Public Health **Policy Makers** State Health Lega Autority Fundi Department CDC - Gap Area

Figure 6. Gaps in Structures that Support Surveillance

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d. Public health misses opportunities to communicate the importance of surveillance to policy makers and the media. A better understanding of surveillance among these constituencies would help ensure adequate funding and a rational legal framework to support it.

E. Other Issues for Consideration

In addition to these specific gaps in the system, we identified a number of cross-cutting issues that need to be addressed. These include:

1. Information Technology. Information technology offers opportunity for improvement across many areas, but significant obstacles exist to its widespread deployment. Support is lacking for existing technologies and current capabilities are uneven across states, localities, and disease areas. Lack of data standards and issues of privacy, confidentiality, and security must be resolved before systemic solutions can be implemented.

2. Widespread Innovation but Limited Sharing. States, localities, and disease areas within the CDC are developing multiple solutions to the same problems around data capture, analysis, and transmission. For example, many states are developing their own systems to integrate data across disease areas. There is a missed opportunity to share information and capture and disseminate lessons learned.

3. Categorical Funding. The historic patterns of categorical funding have impeded the development of a basic surveillance infrastructure capable of meeting the most critical disease threats. The surveillance infrastructure is fragmented and focused on specific diseases rather than on the broad range of threats that face a given population. This fragmentation is both a function of how Congress has funded the CDC and how the CDC allocates money to states and localities. As a result, data systems are incompatible and capacity is uneven across disease areas. The flexibility of federal funding for emerging infections and bioterrorism has been widely praised for its contribution to core capacity, but critical gaps still remain.

CONCLUSION

Numerous gaps in U.S. capabilities for conducting infectious disease surveillance leave the health of the public susceptible to a wide array of threats. The current categorical system is unprepared to deal with some of the most urgent concerns facing the public health system. Specifically, the experts who contributed to our research identified four potential threats, as detailed below.

A. Bioterrorism

Well before the anthrax bioterrorist event, the concept of bioterrorism received a great deal of attention by legislators, government officials, and the press. It is defined as the deliberate spread of infectious diseases. Bioterrorism events can be potentially devastating—they are unpredictable, and their effects could easily overwhelm our medical care system. Strong surveillance is needed to identify these events at the earliest sign in order to trigger an immediate response. Bioterrorism falls outside the scope of most of our current surveillance efforts in that resulting infectious illness cannot be defined in categorical terms.

The framework and gap analysis presented in this paper can inform policy-makers as they develop an investment plan to strengthen the public health system to identify and respond to bioterrorist attacks. The recent anthrax attacks serve to highlight the importance of strengthening key components of our nation's core capacity for infectious disease surveillance, including: staff investigative and response capacity; communication channels between providers and public health officials to ensure individual cases are recognized and treated; and laboratory capacity to identify cases and areas of contamination.

B. Emerging Infections

These include new or resurgent infectious diseases. New Variant Creutzfeldt-Jakob disease (the human disease associated with bovine spongiform encephalopathy or "mad cow" disease) is one recent example. These infections often take providers and public health officials by surprise, leaving the medical and health care communities unarmed to defend against them in the short term. Rigorous surveillance is needed to identify and control such diseases before they become widespread.

C. Drug Resistance

Many infectious pathogens are renowned for their ability to mutate to accommodate changes in the environment. One particularly devastating type of mutation enables pathogens to become resistant to antibiotics—for example, drug resistant tuberculosis has emerged as a major problem around the world. When this situation occurs, pathogens can thrive despite medical treatment. Surveillance is critical to identifying changes in pathogens so that drug development can keep pace with evolving pathogens.

D. Pandemic Influenza

Experts fear the antigenic shift to a new pandemic strain of influenza, such as occurred in 1957 with the introduction of the Asian strain and in 1968 with the introduction of the Hong Kong strain. In each of these instances there was a significant increase in illness and deaths. The essential role of surveillance is to recognize the antigenic shift as quickly as possible so that the new strain can be incorporated into the vaccine.

While these examples represent those threats of greatest concern to surveillance experts, a myriad of smaller-scale, every day threats also persist that can only be addressed through strengthened surveillance capacity.

As the United States faces its first major bioterrorist attack, lawmakers are debating how to improve the nation's capacity to protect the public from what has long been feared, but is now a reality. While bolstering the nation's supply of vaccines and pharmaceuticals is important, it is even more critical to shore up the public health infrastructure—the people, systems, and linkages that work to detect unusual patterns of disease—to investigate sources of outbreaks and to take measures to protect the health of the public. Substantial investment will be critical to ensure sufficient resources are in place at the federal, state, and local levels so that we are prepared for all types of biological threats.

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APPENDIX

Scenario 1: The challenge is to recognize a new respiratory illness. It can have multiple sources, including liquid aerosols. It is transmitted by the airborne route and from person-to-person. The attack rate for exposed individuals is about 30%. Most who have symptoms see physicians. To an experienced clinician, it does not look like typical influenza or other common infections although less experienced clinicians may be misled. It is very debilitating for about a week, but only a small portion of victims require hospitalization, and even fewer die.

Scenario 2: The challenge is to recognize a major change in antimicrobial drug resistance. The organism affected is not one commonly associated with multiple drug resistance and is not thought of as causing major infections in hospitalized or debilitated patients. It is a common cause of mild urinary tract infections, especially affecting young women—so called honeymoon cystitis. It can transmit its unique mechanism of drug resistance to a wide variety of other organisms.

Scenario 3: The challenge is to recognize a serious infection that does not fit the case definitions of any of the major reportable diseases and causes severe debilitation, but not death. This infection's source can be contaminated food or water. The incubation period is approximately 2 to 5 days, and the attack rate is about 30%. Its symptoms include a very unusual and severe headache, severe fatigue, and minor diarrhea. It is very debilitating—people are "wiped out" for at least a week—but physicians typically do not admit patients to the hospital. Few die from it, and the occasional deaths are due to a variety of complications.

Scenario 4: The challenge is to recognize importation of a highly contagious and quite serious viral hemorrhagic fever. The source is an infected individual who travels through several states using a series of crowded common carriers. With this condition, spread occurs during a relatively prolonged period—4 to 7 days before the infected individual becomes quite ill. Attack rates are moderately high, and deaths are very common among those infected.

Scenario 5: The challenge is to recognize an important epidemic involving a common, community-acquired infection. Here, a processor of nationally distributed consumer foods changes its production processes, which leads to ongoing contamination of non-perishable foods with a *Salmonella* strain. The foods are typically used in restaurants and homes. A food item may be ingested within a week, or as long as six or more months, after production. The contaminated foods

have neither a different taste nor appearance, but depending on the way the food is handled at the point of use, it may cause illness in 5% to 30% of people.

Scenario 6: The challenge is to recognize an important change in the epidemiology of an enteroviral pathogen. Imagine that a new purification system for potable and swimming pool water becomes available that produces water with much greater customer satisfaction at much lower cost. As a result, this system is adopted by municipal systems and pool operators relatively quickly over a 1 to 2 year period. Even though the mechanism is unclear, some strains of enteroviruses are not inactivated by this process, and outbreaks of aseptic meningitis and other typical enteroviral illnesses occur sporadically across the nation.

Scenario 7: The challenge is to recognize a change in the epidemiology of sexually transmitted diseases caused by *Chlamydia* that result from changes in sexual practices. The use of a readily available commercial product is widely touted on the Internet and elsewhere as greatly enhancing sexual enjoyment for men and women. Since this product was not intended to be used for this purpose, it has never undergone any relevant testing. Unknown to anyone, use of the product greatly enhances the ease of *Chlamydia* transmission and also seems to increase the seriousness of resulting infections.

References

1. The literature search entailed a review of articles published primarily between 1990 and 1999. Key terms that guided our search included: surveillance; infectious disease surveillance; disease reporting; disease detection; surveillance and technology; epidemics; laboratory surveillance; surveillance and geographic information systems; and disease outbreaks. On-line searches were conducted in three main databases (MEDLINE, HealthSTAR, and HSRProj) and the World Wide Web. Relevance was assessed according to each article's ability to inform the following questions: (1) What is disease surveillance? (2) What are the key characteristics of infectious disease surveillance? and (3) What are the key characteristics of the current domestic surveillance system?

2. These sites were chosen in order to capture a range of characteristics. For example, Oregon is widely perceived as a "best practice" site; West Virginia has recently implemented a number of model initiatives and is predominantly rural; and Baltimore is a large city region and functions independently from the state in which it is located.

3. The conversation guide was designed such that each surveillance expert responded to a somewhat different set of questions. Questions for a particular respondent were chosen based on a combination of the background of each surveillance expert and randomization.

4. These eight goals were identified based on our literature review as well as input from the blue ribbon panel.

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Two Cheers For Employment-Based Health Insurance

David A. Hyman, M.D., J.D.* and Mark Hall, J.D.⁺

Reform, sir, reform? Don't talk to me of reform. Things are bad enough as they are.

-Sir Henry Maudsley

Employment-based health insurance is the Rodney Dangerfield of health policy: it gets no respect from anyone. Liberal enthusiasts of a onepayor system view the existence of employment-based health insurance as a major impediment to the achievement of universal comprehensive coverage.² From the opposite end of the political spectrum, free market enthusiasts attack employment-based health insurance on the grounds that individual preferences are systematically ignored, and cost-quality tradeoffs are inappropriately constrained when employers select coverage for employees.³ Advocates for a patient bill of rights complain that managed care is favored by employers (not employees), and argue that employers are motivated by profits, instead of the best interests of their employees.⁴ Prominent health policy scholars and the media routinely condemn the linkage between employment and health insurance.⁵ Even employees, are at best lukewarm about their role in the coverage market.⁶

Given these unfavorable attitudes, it is not particularly surprising that reforming these arrangements has been a perennial topic on the policy agenda—even though most employed individuals with health insurance obtain their coverage through their employers, and the employment-based market provides coverage for approximately 177 million Americans.⁷ During the past six decades, thousands of pieces of legislation have been

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[‡] An early version of this Article was presented by Professor Hyman as testimony to the Working Group on Challenges to the Employment-Based Health Care System, Advisory Committee on Employee Welfare and Pension Benefit Plans, Department of Labor. We appreciate the helpful comments of Russell Korobkin, Peter Jacobson, and Tom Miller. Norman Stein's gracious invitation to address the Working Group (on which he serves) provided us with the opportunity to address these issues.

introduced at the state and federal levels, seeking reforms ranging from the incremental to the radical. Legislation has sought to change the tax treatment of health insurance premiums, encourage more people to purchase health insurance on their own, partially or completely eliminate employers from the coverage market, mandate all employers to provide coverage, require employers to include specified benefits or providers in their coverage, and the like. Articles supporting and criticizing each of these competing proposals and offering additional reforms fill the pages of medical, legal, economic, and health policy journals.

This Article steps back from this morass of competing proposals and considers the employment-based coverage market from a comparative institutional perspective.⁸ This approach allows us to assess the costs and benefits of the existing system against the likely alternatives, and provide a more balanced foundation for assessing proposed reforms. As the title of this Article suggests, we conclude that the employment-based coverage market deserves "two cheers," and relatively modest incremental changes are all that are required (or for that matter, politically likely, during the foreseeable future) to ensure the continued smooth functioning of the employment-based coverage market.⁹

Our assessment that the employment-based coverage market deserves "two cheers" is unlikely to satisfy most commentators, irrespective of whether they favor a one-payor system, universal adoption of medical savings accounts, or something in between. The score we assign to employment-based health insurance obviously falls well short of perfection. Yet, it is important to keep in mind that perfection is never an appropriate standard for judging real world policies and institutions.¹⁰ Any "reform" of the employment-based coverage market will replace the existing institutional arrangements and problems with new (and not necessarily improved) institutional arrangements and problems.¹¹ Prudent policymaking requires that one has a full appreciation of the advantages and disadvantages of existing arrangements, and a framework for determining whether proposed reforms, on balance, make things better or worse.¹² In this Article, we seek to provide the information and analysis necessary to accomplish both of these goals.

Part I explains how employers ended up occupying such a central role in modern health policy and provides a snapshot of the current coverage marketplace. Part II outlines a number of problems with the current system. Part III provides a comparative institutional perspective on the problems outlined in Part II. Part IV considers the politics of incremental reform, offers a few modest "fixes" to the problems outlined in Part II, and addresses the problem of the uninsured.

I. WHERE WE ARE, AND HOW WE GOT HERE

A. The Rise of Employment-Based Coverage

Employers were initially marginal players in the coverage market, but they quickly assumed a dominant position. In large part, this outcome was simply a historical accident, fueled by federal labor and tax policy. Before World War II, some employers offered early forms of managed care to their workers and families, but these employers were very much the exception.¹³ The medical profession vehemently opposed such "contract" or "corporate" practice, and sought to limit the spread of such arrangements.¹⁴ By one estimate, no more than four million Americans, or approximately 3% of the population, had employment-based coverage in 1930.¹⁵

The first dramatic increase in employment-based coverage came during World War II. Wage and price controls were instituted by the Office of Price Administration in an attempt to deal with inflation.¹⁶ Employer contributions to insurance and pension funds were not counted as wages, and were accordingly excluded from the wage controls. The freezing of cash wages forced employers to compete for scarce labor by enhancing their fringe benefit packages. Health insurance offered a straightforward way for employers to sweeten their compensation package in a manner that would be quite appealing to potential employees.

The second impetus for employment-based coverage was the federal tax code. In 1943, the Internal Revenue Service issued a ruling indicating that the amounts paid by employers for insurance for employees did not constitute income to employees, even though employers could deduct these amounts as ordinary and necessary business expenses.¹⁷ Ten years later, the IRS withdrew this ruling, but Congress amended the Internal Revenue Code in 1954 to expressly exclude employment-based coverage from taxable income.¹⁸ In effect, this asymmetric tax treatment allows employers to purchase health insurance for their employees using employees' before-tax income, rather than forcing employees to purchase it themselves with after-tax income. The amount of the subsidy is a function of the marginal tax rate for any given taxpayer, but its size is larger for higher-income taxpayers because of the progressivity of federal taxation.¹⁹ In the aggregate, this subsidy is worth more than \$100 billion in foregone tax revenue per year, and is the second largest tax expenditure, after home mortgage interest.²⁰ The result is a substantial financial incentive for employees to obtain coverage through their employer if at all possible.²¹

Labor unions were another factor in the rise of employment-based

coverage. During the late 1940s and 1950s, unions aggressively bargained for richer benefit packages, with health insurance at the top of their list.²² In industries in which unions were strong (e.g., manufacturing and public-sector employment), the result was that many subscribers obtained first-dollar insurance coverage and medical care at no out-of-pocket cost to themselves whatsoever.²³ Employers with non-unionized workforces also offered rich benefits to discourage their employees from unionizing.²⁴

B. A Snapshot of the Employment-Based Coverage Market

Although the figures have fluctuated somewhat in the past decade, employment-based coverage seems to have stabilized at approximately 65% of the under-65 population, or roughly 177 million Americans.²⁵ Most employees of large and medium-sized corporations now have access to employment-based coverage, although not all of them choose to take advantage of it.²⁶ Employment-based coverage is much less available to those who work in certain industries (e.g., agriculture, retail, and food service), temporary and part-time employees, and those who work for small businesses.²⁷ Dependents of employees can usually obtain coverage through the working member of the family, but increased cost sharing has caused some erosion of such coverage in recent years. The result of these patterns is that approximately thirty-nine million Americans are uninsured in any given year—even though about 85% of the uninsured live in families headed by an individual who works at some time during the year. More than 50% of the uninsured are full-time, full-year workers, or their family members. The remaining sixty-five million Americans are covered by Medicare, Medicaid, or another governmental program, and thus do not require employment-based coverage.²⁸

Commentators wax poetic about the social role of health insurance, and treat the decision to offer and purchase such coverage in morally weighted terms.²⁹ However, the evidence is fairly clear that potential subscribers approach coverage decisions in traditional economic terms. When faced with a choice of health care coverage, price is the key driver of the decision-making process, and a significant number of individuals who have access to coverage through their employer decline it on the grounds it is too expensive.³⁰

II. PROBLEMS WITH AN EMPLOYMENT-BASED SYSTEM

Most of the difficulties with employment-based insurance stem from the fact that someone other than the ultimate consumer of health care is making most of the decisions about what coverage to purchase and how much to pay.³¹ By selecting particular insurance products to offer their employees, and excluding others, employers necessarily influence what services are covered, and the circumstances under which those services can be delivered. In like fashion, by selecting particular insurance products, employers effectively dictate the scope and nature of the cost-quality-access trade-offs their employees can make.³² Although some employers offer their employees multiple health insurance arrangements, approximately half of employed workers are not offered such a choice.33 Even when multiple plans are offered, there is little ability to tailor coverage to particular needs and tastes.³⁴ The net result is a series of informational, mismatches—between employers preference. and incentive and employees, and between employee groups and individual employees-that play out in the cost and breadth of the coverage that is offered.

A. Heterogeneous Preferences

Because employee preferences with regard to cost, quality, and access are heterogeneous, and employer information as to employee preferences and health care quality is imperfect, the result is that there are predictable disjunctions between the coverage preferences of any given employee and the terms selected by the employer on behalf of the employment-based risk pool as a whole.³⁵ For example, some employees might prefer that their insurance cover more extensive postpartum hospitalization, while others might prefer better coverage of AIDS, and some employees might simply prefer less generous coverage in exchange for a higher take-home salary. The distribution of these preferences will also vary from employer to employer; the employees of a start-up software company in Silicon Valley are likely to want a quite different package of benefits than the employees at an automobile assembly plant in Detroit.³⁶ Whatever the choice, the specification of coverage necessarily implies a series of trade-offs within the risk pool, with significant distributional implications within and across identifiable groups.

B. Incentive Mismatches

Even when there is uniformity of preferences within employee ranks, there are incentive mismatches between employers and employees. An employer may care greatly about conditions that affect its most highly valued employees, but show less consideration for conditions that disproportionately affect employees who are fungible, or work in a division slated for sale or closure. Incentive mismatches also affect issues of quality. Because employers internalize only a portion of the benefits of better quality care, they have less incentive to favor any particular quality enhancement than do employees as a group.³⁷

Stated more concretely, because plans are a "bundled" product aimed at a diverse workforce, the alternatives that any given employer offers frequently do not include desired and desirable features from the perspective of any given employee, while also including features an individual employee may regard as a waste of money.³⁸ Changes in coverage also induce disruption and dislocation costs, whose magnitude is greatest for those with chronic conditions requiring highly specialized care.³⁹ It is commonplace (and completely accurate) to describe these mismatches as a source of market failure in the coverage and delivery markets.

C. Information Imperfections

Additional difficulties are created by the lack of transparency of the employment-based coverage system. Employer contributions are just another form of compensation to employees—and increased costs of coverage result in smaller wages for employees.⁴⁰ However most employees (and some employers) believe that employers are footing the bill for the coverage that employees receive. The result is that employees are relatively indifferent to the cost of their health care coverage (at least to the extent their employer is the one writing the check), while employers are extremely concerned about the cost of providing coverage for their employees. This lack of transparency creates a set-up for conflict between employers and employees about the nature and cost of coverage. Indeed, the lack of transparency probably accounted for much of the backlash against managed care, as employees did not perceive that they had received any benefit from the change, even though they received most of the estimated "savings" of \$300 billion in the form of higher wages.⁴¹

D. Labor Market Dislocations

The linkage of employment and health coverage also creates sequencing difficulties when one changes jobs, or loses a job. Many health insurance policies contain waiting periods or exclusions on pre-existing conditions, which chill job mobility ("job-lock").⁴² A worker might also choose to stay in his current job if the substantive terms of insurance coverage are particularly valuable to the worker or his family, even though another job might offer greater opportunities or a higher salary.⁴³ Similarly, because coverage is linked to employment, individuals who lose their jobs simultaneously lose their health insurance coverage.⁴⁴ Congress

was sufficiently concerned about these problems that it sought to enhance continuity and portability legislatively.⁴⁵

When employers do not offer coverage at all, employees are unable to purchase such coverage on tax-advantaged terms, no matter how much they might desire it. Temporary and part-time workers also have difficulty obtaining coverage because of their transitory connection to any given employer. When these factors are combined with the substantial geographic variation in the distribution and type of employers, the result is that some states have substantially higher rates of uninsurance, simply because of employment demographics in that state.⁴⁶

E. Regulatory Dislocations

Finally, all of these problems are worsened by the haphazard manner in which federal law preempts the traditional forms of regulatory oversight that would apply were the coverage not employment-based. In brief, state insurance commissioners have traditionally regulated the terms of insurance contracts quite aggressively, and state courts routinely employed common law causes of action to encourage insurers to deliver what they promise.⁴⁷ However, the Employee Retirement Income Security Act of 1974 (ERISA) creates a large loophole in this structure by preempting most state-level regulation of health insurance if it is provided in connection with employment,⁴⁸ and by providing only an exceedingly limited set of remedies (lawsuits are, to a first approximation, limited to the value of the denied services). This approach makes sense for protecting pension funds, which was ERISA's primary focus. Health benefits were included in ERISA as an afterthought, with little consideration given to whether the same regulatory framework would work-a problem that became increasingly obvious as managed care came to dominate the coverage market.

The result of this statutory framework is to leave employment-based health insurance effectively unregulated, since ERISA contains no substantive regulation of health benefits. ERISA does provide that the state can indirectly regulate an employee benefit plan if the plan purchases insurance from a state-regulated insurer (an "insured" employee benefit plan). However, only limited forms of regulation are allowed, and many potential tort claims are still preempted. Moreover, if the employer provides its own insurance (a "self-funded" employee benefit plan), the plan is effectively not subject to any state regulation. Thus, so long as coverage is employment-based, ERISA makes it extremely difficult to employ the traditional mechanisms for ensuring accountability—a fact that has helped fuel the drive for a patient bill of rights.⁴⁹

This litany of problems makes it clear why reform of these

arrangements is a popular topic. Yet, initiating such reforms solely on the basis of complaints about the status quo is akin to convicting a defendant after hearing only from the prosecution.⁵⁰ It is one thing to identify shortcomings in employment-based coverage, and quite another to draw the conclusion that any given reform is necessary and appropriate—irrespective of whether the reform is aggressive state and federal regulation, elimination of ERISA preemption, replacing employment-based coverage with a one-payor system, medical savings accounts, or an individual mandate. Instead, a comparative institutional perspective requires that we consider whether employment-based coverage, for all its imperfections, outperforms alternative institutional arrangements. As Professor Neil Komesar concisely noted, "bad is often best, because it is better than the existing alternatives."⁵¹

III. COMPARATIVE INSTITUTIONAL ANALYSIS

A. Advantages of an Employment-Based System

Viewed from a comparative institutional perspective, employers perform several important and under-appreciated functions for employees in the coverage and delivery markets. First, the agency problems noted above often are more theoretical than real. Although the involvement of employers in the coverage market was effectively accidental, they are actually fairly well suited for the position they find themselves in. Surveys and focus groups indicate that employers do a reasonably good job reflecting their workers' values and preferences, just as one would expect in a reasonably competitive labor market.⁵²

Employment-based coverage also helps to solve other types of market imperfections. In particular, employers provide useful search and aggregation functions for their employees in connection with the specification of coverage terms. This process of "informational intermediation" helps compensate for the bounded rationality of individual employees, and ensures that coverage will not be limited to conditions that are salient to employees at the time of purchase.⁵³ Medium and large employers also have personnel departments, which can costeffectively handle coverage design, enrollment, premium collection, and dispute resolution. Many employers have developed as much sophistication and expertise in health insurance as that of most insurers. The result is that employers can bargain aggressively for discounts, serve as an effective advocate for employees who are involved in coverage disputes, and obtain more value for their employees' money than employees could do on their own.⁵⁴

Employers also improve market conditions without even trying. Since employers are offering group coverage, they create significant efficiencies of scale with regard to administrative and marketing costs. This advantage is reflected in the portion of the insurance premium devoted to paying medical costs, rather than going to administrative overhead. Overhead costs for the largest employer groups are typically 5% or less, whereas these costs reach around 20% for smaller groups, and go above 30% for individual purchasers.⁵⁵ Savings of this magnitude allow the purchase of more extensive coverage than otherwise would occur.

Employment-based insurance also promotes more comprehensive coverage by virtue of the substantial tax subsidy associated with such insurance.⁵⁶ Insurance pools naturally tend to suffer from lack of cohesion and stability. It is not a simple matter to form a group that is willing to pool their health insurance expenses and arrange for (and selectively subsidize) insurance, such that almost everyone in the group will opt into coverage. If members of the group have widely varying risk profiles and can obtain comparable coverage outside the group setting, the healthier ones will opt out and purchase individually at a rate cheaper than the average cost for the entire group. In other words, the savings to healthier members from disaggregating the group could well exceed the savings from group economies. In these circumstances, only the tax subsidy makes it significantly more attractive to purchase coverage through one's employer. Therefore, the tax subsidy plays the important role of keeping intact the heterogeneous risk pools that are needed to achieve the administrative efficiencies found in employment-based health insurance.

Healthier members opting out of a group is one form of a more general phenomenon known as "adverse selection." This phenomenon is pervasive in insurance and can cause insurance to become partially or entirely unmarketable. Adverse selection occurs when potential subscribers know more about their individual risks than the insurer knows.⁵⁷ Suppose, for instance, that a health insurer approaches a market assuming that all people of the same age and sex have the same risk of disease or injury and so the insurer prices its product accordingly—say, at \$3,000 for males aged 40 to 45. Naturally, not all men this age have the same risk of illness. Some are in excellent shape, some have average health, and some are already sick. If the insurer is not able to act on this information (or is prohibited from learning it), and if only some people purchase insurance, a disproportionate number of sicker people will subscribe, because those with greater than average risk will find the average price more attractive than those of lesser risk. A pool of sicker-than-average subscribers will obviously end up costing more than \$3,000 per person, so an insurer that

wants to remain solvent will raise its price—say to \$3,500. This does not solve the adverse selection problem, since at any price the insurance is by definition more attractive to higher-risk than to lower-risk subscribers.

Adverse selection exists as an imperfection to some degree in all insurance markets, and it is increased by laws (such as community rating) that require insurers to disregard certain risk factors. Adverse selection discourages the purchase of insurance by some people who would otherwise have chosen to purchase coverage. At the extreme, adverse selection may destroy the market altogether, since the tendency is for prices to migrate towards those that are appropriately charged for the highest risks. Obviously, this price point is unaffordable for many—and a bad deal for most—potential subscribers. One remedy for adverse selection is for insurers to engage in risk underwriting, by learning as much as possible about the risks of individual subscribers and to group and price subscribers according to their actual risks. This process is referred to as risk selection (or risk assessment) and risk rating. The effect is to create multiple, separately priced risk pools that are each stable. In individual health insurance, risk selection is done through questionnaires and medical exams. Ferreting out more refined risk information can be costly. Moreover, this process results in higher-risk people being priced out of the market, and in types of coverage that are more attractive to higher-risk people not being offered at all.

Employment-based coverage offers a partial solution to these problems. Because an employment-based risk pool exists for reasons independent of the demand for coverage, the significance of adverse selection in the coverage market is greatly attenuated. Employers, except for the very smallest "mom-and-pop shops," are not motivated to purchase insurance by specific anticipated health care needs (such as an anticipated pregnancy). Therefore, the insurer can safely assume that the group's future medical expenses will approximate the group's recent experience. This allows the insurer to assess the overall group's average risk simply by observing its claims experience (experience rating), rather than assessing each individual member's risk. More importantly, because the group exists for non-insurance reasons, new members of the group will not be higherthan-average risk and group-leavers will not be lower-than-average risk. In other words, group members will not select in or select out of the group just because of the insurance, so the group's risk will remain stable. In combination, this means that coverage can be written in the employmentbased market at a considerably lower cost than would be the case if each member of the pool presented individually and requested coverage.

Employment-based groups are also cost-effective vehicles for

insurance, because workers (and, to a lesser extent, their beneficiaries) are healthier on average than non-workers. This demographic reality lowers the cost of coverage still further. As a consequence of these economic advantages, insurance purchased by employees through large employers costs about one-third less than equivalent coverage would cost in the individual insurance market, if it were available—and equivalent coverage is often not available at all.⁵⁸

Employment-based coverage is also the nexus for cross-subsidization within pre-existing risk groups. Because employment-based coverage is not risk-adjusted or underwritten within the risk pool, there are, by definition, systematic cross-subsidies flowing within the pool.⁵⁹ Although these arrangements fall well below the degree of social solidarity desired by advocates of one-payor systems, they are real, and long-standing.⁶⁰ The success of employment-based coverage in maintaining these internal cross-subsidies should be contrasted with the difficulty that states and the federal government have encountered in mandating or maintaining such cross-subsidization.⁶¹

As private actors, employers also have greater flexibility in the design and implementation of cost-cutting and quality-enhancing initiatives than public payors. Public payor initiatives typically trigger opposition and lobbying; private payor initiatives are (relatively) insulated from such processes.⁶² In like fashion, public payors are subject to constitutional and statutory norms of uniformity and openness, while private payors have greater freedom to provide different benefits to different customers and to define their obligations and methods of dispute resolution by contract.⁶³

Employment-based coverage also neatly maps onto traditional American attitudes regarding government.⁶⁴ The large public programs (Medicare and Medicaid) are reserved for those who are too poor or highrisk to have market options.⁶⁵ When responsibility for coverage is handled by private parties, the government's access to sensitive information on its citizens is sharply constrained. Employees are less than thrilled that their employers have access to this information, but they are even less enthusiastic about the government having the information. Similarly, when employers are responsible for making coverage arrangements, the government has considerably more limited involvement than would otherwise be the case—a feature that is particularly desirable if one doubts the competence and compassion of a governmental bureaucracy.⁶⁶

Finally, employment-based coverage may allow for more innovation with regard to coverage arrangements. Although Medicare was responsible for a number of significant innovations in payment patterns (e.g., prospective payment via diagnosis-related groups (DRGs) and the
resource-based relative value scale (RBRVS)), such arrangements tend to be all-or-nothing developments. Because of the large number of employers, coverage innovations can develop in a bottom-up fashion. For example, a number of employers are flirting with moving from "defined benefit" coverage (in which the employer picks one or more coverage options for all of its employees) to a "defined contribution" arrangement (in which employees receive a specified amount to be used for the purchase of whatever coverage they desire).⁶⁷ These proposals coincide with the emergence of web-based systems that individuals can use to shop for such coverage.⁶⁸ Although such arrangements create problems of risk adjustment, they hold out the potential of eliminating many of the previously outlined agency problems associated with the involvement of employers in the coverage market.

An even more intriguing development is the interest of some employers in using their market power to force providers to improve the quality of care they are providing. Historically, individual patients have paid little attention to the problem of low quality care, since they tend to rate the quality of care they personally receive quite highly.⁶⁹ Such confidence is unwarranted; the quality of American medicine varies widely. Some services are over-utilized, others are under-utilized, and utilization rates vary from place to place in unexplained ways.⁷⁰ Patients are also frequently injured as a result of medical treatment. The Institute of Medicine estimated that between 44,000 and 98,000 deaths per year result from medical mistakes—making medical error the eighth leading cause of death in the United States.⁷¹ Every year, medical errors kill more people than motor vehicle accidents, breast cancer, and AIDS.⁷²

Although these problems are generally not salient to individual recipients of health care, employers have started to address them.⁷³ Predictably enough, they are using economic incentives to encourage providers to ensure the quality of care they provide, instead of paying providers based on variables that bear little or no relationship to the quality of care that is rendered (e.g., the amount of time a provider spends with a patient, the number of patients a provider treats, the number and type of procedures a provider performs, the number of weeks a provider is employed, or the number of patients in a provider's practice).⁷⁴ The acknowledged leader in this campaign to develop "value-based purchasing" is the Pacific Business Group on Health (PBGH), a consortium of employers who collectively spend more than \$3 billion annually on health care for nearly three million employees. In 1995, PBGH began negotiating performance contracts with the HMOs with whom they dealt. HMOs that failed to meet targets on a variety of performance measures were required

to forfeit a small portion of their fees.⁷⁵ Once performance was tied to compensation, the quality of care that was rendered started to improve.⁷⁶ PBGH's success has led other groups to copy its strategy.⁷⁷

Employers are also taking steps to address the problem of medical errors. The Leapfrog Group, a consortium of employers, has pledged that its members will purchase health care services only from providers who have made certain specified investments in error reduction. Hospitals must adopt computerized systems for prescribing medicines, patients requiring particularly complex procedures must be referred to hospitals with the highest survival rates, and hospitals with intensive care units must provide twenty-four hour staffing by critical care physicians.⁷⁸ Each of these initiatives has been demonstrated to improve patient outcomes, and there appear to be substantial financial savings associated with implementing them. Indeed, Leapfrog Group estimates indicate that these three improvements could save up to 58,300 lives per year and prevent 522,000 medication errors, if implemented by all non-rural hospitals in the United States.⁷⁹

To be sure, these initiatives are small steps by only a few employers.⁸⁰ However, even these baby steps are more than any federal or state health program has been able to do—or is likely to do, given the political dynamics under which these programs operate.⁸¹ When the New York Department of Public Health suggested the use of performance-based compensation for cardiac surgery, physicians and hospitals pressured legislators to prohibit such arrangements.⁸² Medicare has had limited success with its attempts to designate "centers of excellence" for cardiac and orthopedic surgery, as providers have claimed that the centers are being selected primarily on grounds of cost, rather than quality.⁸³

B. Problems with Reforms

Although the employment-based coverage market has all of the weaknesses outlined previously, a fair comparison requires one to consider the analogous weaknesses of any proffered "reform." It is easier to identify agency conflicts and bounded rationality than it is to solve such problems. Any system of preference aggregation invariably creates a problem with preference mismatch—and the larger the group being aggregated the worse the problem. Any given "reform" will not solve all of the problems found in the employment-based market, and it may well make some of them worse—particularly when one factors in the likelihood of legislation by anecdote, symbolic blackmail, and agency capture.

Enthusiasm is not a sufficient precondition to ensure that "reforms" improve on the status quo. The critical institutional competence question

is whether those who will be designing and running the system after the "reform" has been implemented have the necessary information, preferences, and incentives to outperform the employment-based market. In economic terms, the issue is which agency relationship is less imperfect across the relevant dimensions of cost, quality, and access. In reality, most of the "reforms" suffer from the same weaknesses as the employment-based coverage system—and when a "reform" performs better on one aspect of the incentives/information/preferences mismatch triad, it usually does worse on another aspect of the triad. Alternatively, the "reforms" may trigger adaptive responses that are socially inefficient, and make everyone worse off. Thus, it is far from clear that any of the reforms will actually improve the status quo—particularly if the reforms are not subject to the market test of allowing affected individuals to determine whether they prefer the status quo ante.

For example, if employment-based health insurance is abandoned, adverse selection will become a much more serious problem. Risk selection (both favorable and unfavorable) is likely to require regulatory attention.⁸⁴ If each person is allowed to contract for the precise coverage he or she anticipates needing, those seeking to purchase any given policy will disproportionately be those expecting to make claims under the policy. As costs for that particular policy rise to reflect claims experience, those who do not value the specified coverage will make alternative arrangements—triggering still-greater increases in premiums and more defections from the risk pool. In short order, many forms of coverage will be unavailable at any price.

The problems presented by risk selection are illustrated by the difficulties potential subscribers currently encounter purchasing health insurance in the individual market. A recent study approached nineteen insurers in eight different states with a variety of hypothetical purchasers who had common, but not terribly serious, health problems—for example, a person with hay fever, a person with a bad knee from an old sports injury, a child with asthma and ear infections, and an overweight smoker with high blood pressure. The study found that 90% of the time, full coverage was not available at standard rates. Either coverage was refused, premium surcharges averaging 38% were imposed, or the condition in question was excluded.⁸⁵

Employers represent an effective solution to the risk selection collective action problem. If large numbers of people leave the employer coverage market, legislators and regulators will need to address the issue most likely by reforming how insurance is sold in the individual market and mandating a menu of benefits. Unfortunately, when legislatures mandate benefits, they simply replace one set of preference aggregation problems (at the employer level) with a worse set of preference aggregation problems (because the process is conducted at the state or federal levels), coupled with the distorting consequences of symbolic blackmail and private self-interest on the substantive content of the mandates.⁸⁶ Other market reforms, such as guaranteed issue, open enrollment, and versions of community rating essentially attempt to replicate for the individual market the risk pooling and efficiencies that currently exist in the employer market. However, the technical problems in accomplishing this goal are much greater than the current models that exist in the small group market.⁸⁷ In the small-group market, employers' role in forming insurance pools and selecting coverage helps to solve the adverse selection problems created by restricting insurers' ability to underwrite according to health risk. In the individual market, however, adverse selection problems become insurmountable. States that have required versions of open enrollment and community rating for nonemployer sponsored health insurance have seen insurance prices rise steeply and rates of coverage drop significantly.⁸⁸

Many advocates of non-employer based insurance point to private purchasing associations as the solution to the problems in the individual market. They contend that a variety of different pools, resembling current discounting arrangements for trade association and professional groups, could, in competition with each other, replicate the role that employers play in negotiating lower rates and achieving economies of scale.⁸⁹ Although there is force to these arguments, considerable technical difficulties exist in determining how these hybrid entities would operate at the border of the individual and group markets without disrupting either market. Advocates argue that these association pools should be protected from regulatory mandates that do not apply to large employers, and these pools should be allowed to set their rates according to the group's overall claims experience, as is done for large employers, in order to have an incentive to lower costs and bargain for better rates. If this is done, however, these private associations are likely to draw off the better risks from the individual and small-group markets, possibly causing them to collapse into high-risk pools. Also, different associations offering similar coverage based on the risk profile of people who happen to belong to each pool creates a turbulent market dynamic in which people continually shop to join an association in which most people are healthier than they are. Finally, initial experience with existing insurance cooperatives indicates that they only marginally improve economies of scale. Transaction costs remain high because each subscriber has to be dealt with individually,

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rather than a single purchaser acting on behalf of an entire group.⁹⁰ In short, voluntary pools contain only a shadow of the efficiencies created by employment-based pools. At bottom, they lack both the cohesion and the economies of scale in employment-based pools.

Even if the individual market can be successfully reformed, nonemployment-based coverage would create significant risk adjustment problems. If insurance purchase is not mandated, healthier people will drop coverage. Subsidies are required for those who cannot afford coverage, but the subsidies must be risk adjusted to prevent insurer "redlining" of subscribers whose anticipated health costs exceed the allowable premium. The science of risk adjustment is far from being perfect, despite two decades of development—and its complexity is likely to rival that of other administered pricing systems such as DRGs.⁹¹

A single-payor system addresses some of these problems (particularly adverse selection), but it worsens others. In particular, the problem of preference aggregation is substantially worsened when everyone in a state (or in the nation) is included in a single risk pool covered by a single benefits package-with the substantive content of that benefits package greatly influenced by political lobbying, symbolic blackmail, and selfinterest.⁹² Single-payor systems are also uniquely vulnerable to larger budgetary pressures, as the amounts available to pay for health care are determined every year based on how effectively health care can compete with other budgetary priorities.⁹³ Many Americans are also suspicious of the public bureaucracy, which will be required to administer such programs. Finally, once the government is a monopsony purchaser, it must navigate the complexities of setting prices, picking qualified providers, and making long-term capital investment decisions. Each of these decisions creates major coordination problems that separately, and in combination, have the potential to increase cost and undermine quality and access. More generally, there are substantial hazards from both under-payment and over-payment, and little probability of convergence toward the "right rate" over time.⁹⁴

IV. WHERE DO WE GO FROM HERE?

A. The Logic of Incremental Reform

There are serious collective action problems associated with building the necessary support for enacting sweeping reforms. Machiavelli framed the problem quite neatly:

There is nothing more difficult to take in hand, more perilous to

conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things. Because the innovator has for enemies all those who have done well under the old conditions, and lukewarm defenders in those who may do well under the new. This coolness arises partly from fear of the opponents, who have the laws on their side, and partly from the incredulity of men, who do not readily believe in new things until they have had a long experience of them.⁹⁵

Given this dynamic, it is not at all surprising that periods of sweeping reform (e.g., the New Deal and the Great Society) are relatively rare. Institutional and political considerations also make it hard for anything but incremental changes to emerge from the legislative process—and implementation raises additional barriers.⁹⁶ The repeated failure of attempts to create a national health care system testify to the difficulties that confront aspiring reformers. In health care, there are too many competing vested interests, and too few people who are fundamentally dissatisfied with their coverage, for comprehensive reform to be politically viable under ordinary circumstances.⁹⁷ Not surprisingly, reform enthusiasts have turned their attention to incremental reforms.⁹⁸ Given this dynamic, we believe that incremental reforms are all that is likely to emerge from the political process during the foreseeable future.⁹⁹

B. Some Incremental Reforms of Employment-Based Insurance

It is fair to ask what changes, if any, we would make in the employment-based coverage market. We believe that several important changes will help ensure the continued smooth functioning of the employment-based market, while simultaneously addressing some of the problems identified previously. However, we do not fully agree on all of the details regarding the specific changes that we believe are appropriate, and on the degree of enthusiasm we each have for particular proposals. Also, we hasten to add that our modest "fixes" will not completely solve the problems identified previously, and they will create new problems of their own-but, as noted previously, the right question is whether, on balance, these "fixes" make things better when assessed across all the relevant parameters. We suggest three specific reforms: (1) changing the tax subsidy so that those without access to employment-based insurance can enter the coverage marketplace on more equal footing than is currently the case; (2) amending ERISA to create more sensible state and federal regulatory and liability regimes; and (3) encouraging the use of purchasing pools.

1. Tax Subsidy Reform. There are a wide variety of ways in which the

tax subsidy can be fixed, depending on what one wants to accomplish, and how much one wants to spend.¹⁰⁰ Most proposals start with providing tax credits to workers who currently do not have employment-based coverage. Other proposals include the self-employed or everyone who might want to private insurance. Depending on the specifics, such purchase arrangements can effectively create a partial voucher system for the purchase of health care coverage, and eliminate the horizontal and vertical inequities associated with the current system.¹⁰¹ However, the more extensive the tax credits, the greater the potential for adverse selection, as younger and healthier employees can suddenly exit existing risk pools. Therefore, we suggest that tax credit proposals should initially focus on those who do not currently have access to employment-based coverage. Beyond that group, we believe that such reforms should be implemented gradually, in order to evaluate the effect on existing risk pools. The advantage of this approach is that it provides a market test of the comparative advantage (if any) of employers in structuring and administering the coverage market, while simultaneously addressing the problem of the uninsured.

2. ERISA Reform. Our second, not-so-minor, repair is to amend ERISA, with due care for the competing considerations of federalism, the varying need for regulatory oversight of different parts of the employmentbased coverage market, and the issue of managed care liability. This subject is far too complicated for us to address in this limited space, and we do not fully agree on the specifics of this "repair." However, we do agree on several basic principles:

a. Existing law treats coverage quite differently, depending on whether it is individual, employer-purchased, employer-self-funded, or sponsored by a religious or governmental employer. Such divisions are wholly artificial, and create distorting incentives in the coverage market. The choice between state and federal regulation should not turn on such fortuities and quirks. Accordingly, the regulatory framework should be revised to treat "like" coverage alike, irrespective of the context through which it is secured.

b. States should have greater leeway to regulate employment-based health insurance, with a continuing role for federal oversight. State authority makes sense where the issues and solutions are likely to vary regionally, along with social and economic conditions. Experimentation and competition among state regulatory regimes is also beneficial in its own right, for the familiar reasons captured in the slogan "laboratory of the states."¹⁰² On the other hand, many important innovations in coverage and delivery arrangements likely would not have occurred without the "breathing room" created by ERISA preemption.¹⁰³ Also, national uniformity is sometimes highly

desirable, and some forms of state regulation will undoubtedly be unwise and unduly burdensome. In keeping with these considerations, federal preemption should occur on a more targeted basis, instead of being sweeping and presumptive.

c. Health insurers should not be virtually immune from certain forms of liability because of the accident of ERISA preemption. A liability scheme should be devised that sets sensible default rules for allocating responsibility for medical error throughout the various components of managed health care systems, but that leaves the parties (e.g., providers, payors, and subscribers) free to reallocate this responsibility by contract. One of these default rules is that employers should not be subject to managed care liability solely by virtue of their role in selecting, designing, or paying for health insurance.

3. Purchasing Cooperatives. Finally, we suggest that purchasing cooperatives or associations be made more widely available to individuals and employers. In order for this to occur, the complex and obscure regulatory treatment of these association pools should be clarified and streamlined, especially when they cross product and geographic market boundaries. More specifically, federal or uniform state law should more clearly define whether insurance sold through pooled arrangements is treated as individual or group insurance. If it is treated as group insurance, then the law should define whether it is small or large group insurance, and, if the latter, the law should delineate the appropriate type for oversight of self-insured arrangements. To avoid disrupting existing employment-based markets, care must be taken to prevent purchasing pools from being used as vehicles for risk selection. Options for addressing this problem include requiring that subscribers make longer-term commitments to association pools, or limiting the circumstances under which subscribers can join or change these pools (e.g., only every three years, or upon changing jobs or moving to a new area).

C. Whither the Uninsured?

What then of those who are left out of the employment-based system? Critics of employment-based coverage typically treat the existence of the uninsured as a moral trump card, justifying immediate and comprehensive reform regardless of the social and economic costs. We agree that addressing the problem of the uninsured is an appropriate reform objective, and we have proposed the use of tax credits to address the problem. However, we believe that the relationship between the employment-based coverage market and the uninsured cannot be resolved on the basis of moralizing. Employers provide coverage (or fail to do so) out of self-interest, and employees accept or decline coverage after making

a similar assessment. Employers operate in a competitive labor market and they are no more morally blameworthy for failing to offer insurance to their employees than they are blameworthy for not paying their minimum wage employees more than minimum wage. Similarly, employees who decline to accept coverage either assess their risks differently, or simply have a better use for their money than buying coverage.¹⁰⁴ There is no compelling theoretical or practical reason to treat all of these decisions, which occur in the shadow of a competitive labor market, as a failure of employers or of the employment-based coverage market.

The availability of employment-based pooling mechanisms may (or may not) offer the best opportunity to address various social problems, but this possibility should not be viewed as creating a moral obligation on the part of employers to meet the social needs that our society has proven unwilling to address, despite repeated opportunities to do so. As Professor Mark Pauly observed:

[T]he worsening of the lot of the uninsured under market competition, if it occurs and is not offset by government, would not be an example of market failure. Rather, it would be an example of serious 'government failure' (at least in the sense of citizens collectively making a bad decision), an example of political failure, and perhaps of moral failure. Markets would be doing what they do best. It would be government that would be failing to do what it should do. Market competition will have abolished a type of charity that citizens, when faced with the challenge to pay for it explicitly and consciously, determined to be not worth its cost.¹⁰⁵

CONCLUSION

It is not all that hard to envision reforms that, had they been adopted much earlier, might well have turned out to be superior to the status quo. Unfortunately, the transition costs and social dislocations in discarding the existing system are likely to be enormous.¹⁰⁶ It may appear intellectually unsatisfying to settle for an imperfect institutional arrangement simply because it happens to be the one in place—particularly when the current system arose largely by accident. However, the history of attempts at national health insurance reform is an unhappy one, and human beings appear to be psychologically hard wired to prefer the status quo.¹⁰⁷

More importantly, any significant change in the existing framework is likely to prompt massive adjustments. Employers are already exceedingly skittish about their role in the coverage market, and they can only be pushed so far. Consider the impact of Financial Accounting Standard 106, an accounting ruling effective in 1993 that required employers to carry as a

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current liability on their balance sheets their promises of future health benefits for retirees. This relatively minor change prompted some employers to drop retiree health benefits altogether and many more to scale back the extent of those benefits.¹⁰⁸

The debate about the competing patient bills of rights reflects similar concerns. A major concern in the debate is whether increasing employers' risk of managed care liability will prompt them to drop coverage altogether.¹⁰⁹ Most of the competing bills have strong language intended to allay this concern, reflecting that the risk is taken seriously on both sides of the political spectrum. We should expect widespread disruptions—both intended and unintended—when wholesale reform of the employment-based system is undertaken.

On balance, the existing system, as imperfect as it is, may be the best we can do under the circumstances. One good indicator of this is that, when asked, most employees would prefer that their employers continue their role in selecting health insurance.¹¹⁰ This does not mean that the employment-based market cannot be improved through judicious market-enhancing initiatives. Yet, the truth of the matter is that an employment-based coverage market does have real strengths, even in its current form, and the proposed "reforms" have their own weaknesses, which any rigorous assessment of the alternatives must weigh in the balance. The fact that the existing system delivers a range of coverage and delivery options to 177 million Americans is itself a strong point in its favor, even without factoring in the transition costs to the brave new world offered by reform advocates.

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3. See EMPOWERING HEALTH CARE CONSUMERS THROUGH TAX REFORM (Grace-Marie Arnett ed., 1999); Stuart Butler & David B. Kendall, Expanding Access and Choice for Health Care Consumers Through Tax Reform, 18 HEALTH AFF., Nov.-Dec. 1999, at 45, 46.

4. David A. Hyman, Regulating Managed Care: What's Wrong with a Patient Bill of Rights, 73 S. CAL. L. REV. 221, 246 (2000).

5. See, e.g., Alain С. Enthoven, Consumer-Centered vs. Job-Centered Health Insurance, 57 HARV. BUS. REV. 141, 151 (1979) ("There is little to lose and much to gain by cutting today's link between jobs and health insurance."); Victor R. Fuchs, The Clinton Plan: A Researcher Examines Reform, 13 HEALTH AFF., Spring 1994, at 102, 110 ("We must disengage health insurance from employment. This tie never had a rational basis.... Sooner or later, the inequities and inefficiencies associated with employment-based health insurance will become so apparent as dictate to E. disengagement."); Uwe Reinhardt, Employer-Based Health Insurance: R.I.P., in THE FUTURE U.S. HEALTHCARE SYSTEM; WHO WILL CARE FOR THE POOR AND UNINSURED?

325, 348 (Stuart H. Altman et al. eds., 1998) ("On balance, it can be asked whether a system with so many inherent flaws merits shoring up through public policy—its numerous virtues notwithstanding—or whether it had not best be left to its own slow demise."); Jennifer Steinhauer, *Hidden Barriers to Health Coverage*, N.Y. TIMES, Oct. 19, 2001, § 3, at 11 (presenting trade-offs associated with employer involvement).

6. See S. SILOW-CARROLL ET AL., THE STATE OF EMPLOYMENT-BASED HEALTH COVERAGE AND BUSINESS ATTITUDES ABOUT ITS FUTURE (2001) (depicting lukewarm support of employers for continued involvement in coverage market); James Robinson, The End of Managed Care, 285 JAMA 2622, 2623 (2001) ("Employers now purchase ever less employee satisfaction at an ever-growing price.... While many employers remain committed to funding health insurance...the trend is to offer information, options, and partial financial support, but to otherwise get out of the decision-making position in health care."); Interview by Patrick Mullen with Regina Herzlinger, Professor, Harvard Business School (May 1998) available at http://www.managedcaremag.com/archives /9805/9805.qna_herzlinger.shtml ("Employers are saying, 'Look, I've got a business to run here, I can't run the health care business and my own business.").

7. Jon R. Gabel, Job-Based Health Insurance, 1977-1998: The Accidental System Under Scrutiny, 18 HEALTH AFF., Nov.-Dec. 1999, at 62; see generally Robert Kuttner, The American Health Care System: Employer-Sponsored Health Coverage, 340 NEW ENG. J. MED. 248 (1999).

8. See generally NEIL K. KOMESAR, Imperfect Alternatives: Choosing INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY (1994) (outlining comparative institutional analysis).

9. See infra Part IV.

10. See RICHARD EPSTEIN, SIMPLE RULES FOR A COMPLEX WORLD 32 (1995) ("First best solutions are rarely if ever, possible; thus the beginning of wisdom is to seek minimize rules that the level of imperfections, not to pretend that these do not exist. No contract, no association is ever bullet proof: no matter what rights, duties, institutions and remedies are chosen, in some circumstances they will be found wanting. Bad outcomes are therefore consistent with good institutions and we cannot discredit these institutions with carefully selected illustrations of their failures. Counterexamples may be brought bear against any set of human to institutions. The social question, however, is concerned with the extent of the fall from grace. The fact of the fall should be taken as a necessary truth, not a shocking revelation. Perfection is obtainable in the world of mathematics, not in the world of institutions."): human Harold Demsetz. Information and Efficiency: Another Viewpoint, 12 J.L. & ECON. 1, 1 (1969) ("The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing 'imperfect' institutional arrangement. This nirvana approach differs considerably from a comparative institution approach in which the relevant choice is between alternative real institutional arrangements.").

11. See supra note 1.

12. Indeed, one of the shortcomings of the managed care backlash has been the failure of most commentators to appreciate the benefits of existing arrangements and the trade-offs associated with the proffered

alternatives. Instead, the general tactic (exemplified by the debates over gag clauses and drive-through deliveries) has been to offer a highly unrepresentative anecdote, and bemoan the defects in the system that it purportedly reflects. See generally David A. Hyman, Managed Care at the Millennium: Scenes From A Maul, 24 J. HEALTH POL., POL'Y & L. 1061 (1999) legislative (presenting evidence that initiatives regarding gag clauses, drivedeliveries, and through access to emergency care are misconceived); Hyman, supra note 4, at 237-44 (outlining the atypical nature of the anecdotal evidence relied upon by Congress in framing patient protections against managed care); David A. Hyman, Drive-Through Deliveries: Is "Consumer Protection" Just What the Doctor Ordered?, 78 N.C. L. REV. (1999)(providing in-depth 5 an examination of the merits of consumer protection legislation against "drivethrough deliveries."); David Mechanic, The Managed Care Backlash: Perceptions and Rhetoric in Health Care Policy and the Potential for Health Care Reform, 79 MILBANK Q. 35, 53 (2001) ("The ongoing public debate often does not accurately convey the key issues or the relevant evidence. Important perceptions of reduced encounter time with physicians, limitations on physicians' ability to communicate options to patients, and blocked access to inpatient care, among others, are either incorrect or exaggerated.").

13. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 200-06 (1982).

14. Id. at 203-09.

15. See Robert B. Helms, The Tax Treatment of Health Insurance: Early History and Evidence, 1940-1970, at 8 in EMPOWERING HEALTH CARE CONSUMERS THROUGH TAX REFORM, *supra* note 3. The population of the United States in 1930 was 122,288,177. *See* Inter-university Consortium for Political and Social Research, Census Data for the Year 1930, *at* http://fisher.lib.virginia.edu/cgi-local/ensusbin/census/cen.pl?year=930.

16. See INST. OF MED., EMPLOYMENT AND HEALTH BENEFITS: A CONNECTION AT RISK 70 (1992).

17. See Helms, supra note 15, at 11.

18. See SHERRY GLIED, REVISING THE TAX TREATMENT OF EMPLOYER-PROVIDED HEALTH INSURANCE 4 (1994); see also I.R.C. § 106 (1986) ("Gross income [of an employee] does not include contributions by the employer to accident or health plans."); I.R.C. § 3121 (1986) (similarly excludes the employer's contribution from payroll taxes).

19. See Helms, supra note 15, at 10; John Sheils & Paul Hogan, Cost of Tax-Exempt Health Benefits in 1998, 18 HEALTH AFF., Mar.-Apr. 1999, at 176, 179, 181 (modeling tax subsidy and concluding that it is "heavily skewed toward high-income groups," with 68.7% of the total subsidy going to the 36% of the population with incomes greater than \$50,000.).

20. See Jay Soled, Taxation of Employer-Provided Health Coverage: Inclusion, Timing and Policy Issues, 15 VA. TAX. REV. 447 (1996) (estimating \$74 billion in foregone taxes); Sheils & Hogan, supra note 19, at 178 (presenting estimate that tax subsidy totals \$124.8 billion); NAT'L HEALTH POL'Y FORUM, ISSUE BRIEF NO. 728, Retooling Tax Subsidies for Health Coverage: Old Ideas, New Politics, http://www.nhpf.org/cfm/ register.cfm (estimating \$96 billion in federal and \$12 billion in state foregone taxes).

21. Congress has partially leveled the playing field, by allowing self-employed

taxpayers to deduct a percentage of their payments for health insurance policies. I.R.C. § 162(1)(B) (1986). Currently, the applicable percentage is 60%, but it is scheduled to increase to 100% in 2003. However, this approach necessarily excludes individuals who are not selfemployed, even if their employer does not offer coverage.

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23. CALIFANO, supra note 22, at 13. ("Like most large companies with employees represented by the United Automobile Workers and such other big unions as the United Steelworkers, Chrysler had allowed the collective-bargaining process to produce a health care benefit package for everything from coronary bypass surgery to fixing ingrown toenails, with no incentive for its employees to buy prudently.").

24. *Id.* at 45 ("First-dollar coverage plans spread like an infectious flu through a crowded elementary school—not only among union employees, but among nonorganized white-collar workers as well.").

25. See Stephen H. Long & M. Susan Marquis, Stability and Variation in Employment-Based Health Insurance Coverage, 1993-1997, 18 HEALTH AFF., Nov.-Dec., 1999, at 133; ROBERT J. MILLS, U.S. CENSUS **BUREAU HEALTH INSURANCE COVERAGE: 2000** (Sept. 2001). available at http://www.census.gov/prod/2001pubs/p 60-215.pdf.

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27. CATHY SCHOEN & KAREN DAVIS, THE COMMONWEALTH FUND, ISSUE BRIEF: EROSION OF EMPLOYER-SPONSORED HEALTH INSURANCE COVERAGE (1998), http://www.cmwf.org/programs/insuranc e/schoen_erosion_ib_297.asp.

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30. See Lynn Etheredge et al., What Is Driving Health System Change?, 15 HEALTH AFF., Winter 1996, at 93, 98 ("The evidence shows that individuals tend to select lowerprice plans from employers' multiplechoice offerings and that even small premium differences can drive enrollment shifts among health plans."); M. Susan Marquis & Stephen H. Long, To Offer or Not to Offer: The Role of Price in Employers' Health Insurance Decisions, 36 HEALTH SERVICES RES. 935 (2001); Catherine G. McLaughlin, Employers as Agents for Their Employees, 36 HEALTH SERVICES RES. 827 (2001); Roger S. Taylor, Commentary, 56 MED. CARE RES. & REV. 60, 62 (1999) ("[T]he majority of consumers were willing to trade the ability to choose providers for a reduction in outof-pocket costs.... This helps explain why, when offered both a fee-for-service plan and a more managed care plan...the majority chose managed care."); Kenneth E. Thorpe & Curtis S. Florence, Why Are Workers Uninsured? Employer-Sponsored Health Insurance in 1997, 18 HEALTH AFF., Mar.-Apr. 1999, at 213, 217 (finding that workers who were eligible for health insurance and rejected it mostly did so because of its high cost); see also supra note 26. As with all preferences, employees differ in their enthusiasm for trading choice for lower prices. See Ha T. Tu & Peter Cunningham, Strong Opinions Held About the Tradeoff Between Choice of Providers and Cost of Care, 4 CENTER FOR STUDYING HEALTH SYSTEM CHANGE: DATA BULLETIN, 1 (1997) available at http://www.hschange.org/CONTENT/93.

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34. MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS § 7 (1997).

35. See Hyman, supra note 4, at 226-27; Russell Korobkin, The Efficiency of Managed Care "Patient Protection" Laws: Incomplete Contracts, Bounded Rationality, and Market Failure, 85 CORNELL L. REV. 1 (1999).

36. Catherine G. McLaughlin, Health Care Consumers: Choices and Constraints, 56 MED. CARE RES. & REV. 24, 25 (1999) ("While health insurance is but one factor in firm choice, it is not difficult to believe that young, single males may deliberately choose to supply their labor to a small, high-tech firm that offers no health insurance in exchange for higher wages, and that a young male with similar skills but two small children and a wife who does not want to enter the labor market may instead supply his labor to IBM, earning a lower salary, but receiving a rich family

health insurance package at a large group rate."). Once one is actually employed, it is not clear how many people will be willing to change their jobs because the coverage is not to their liking. See George Annas, Patients' Rights in Managed Care—Exit, Voice, and Choice, 337 NEW. ENG. J. MED. 210 (1997). However, to the extent employee satisfaction was a factor in offering coverage in the first place, it is unclear why employers would suddenly start selecting coverage options that alienate their employees.

37. See Thomas Bodenheimer & Kip Sullivan, How Large Employers are Shaping the Health Care Marketplace-Part II, 338 NEW Ĭ. Med. 1084. 1087 ENG. (1998)("[E]mployers do not necessarily represent the best interests of their employees."); Hyman, supra note 4, at 233 ("Quality is difficult to assess, let alone value-and employers and employees are likely to differ on the appropriate mix of cost, quality, and access, even before illness strikes."). But see Fernando Montenegro-Torres et al., Are Fortune 100 Companies Responsive to Chronically Ill Workers?, 20 HEALTH AFF., July-Aug. 2001, at 209 (presenting evidence indicating that large employers are doing a good job, in many instances better than Medicare, in dealing with chronically ill employees and dependents).

38. See Judith R. Lave et al., Changing the Employer-Sponsored Health Plan System: The Views of Employees in Large Firms, 18 HEALTH AFF., July-Aug. 1999, at 112, ("[B]ecause employers sponsor only a limited number of health plans, some employees may be forced to 'buy' more or less health insurance than they want.").

39. A change in the coverage offered by an employer can result in employees suddenly discovering that their health care providers are no longer "in the network," and they must either pay more to stay with their existing provider, or find a new provider. See Thomas Bodenheimer & Kip Sullivan, How Large Employers are Shaping the Health Care Marketplace—Part I, 338 NEW ENG. J. MED. 1003, 1007 (1998) (describing such switching as "disruptive" and "intolerable").

40. See MARK PAULY, HEALTH BENEFITS AT WORK: AN ECONOMIC AND POLITICAL ANALYSIS OF EMPLOYMENT-BASED HEALTH INSURANCE (1997); Linda J. Blumberg, Who Pays For Employer-Sponsored Health Insurance?, 18 HEALTH AFF., Nov.-Dec. 1999, at 58.

41. Given this perspective, it is not surprising employees pressured that legislators to address these problemsoften basis of on the highly unrepresentative anecdotes. See Hyman, supra note 4, at 237-41. There is also an important public choice aspect to the story as well, because most of the patient protections turn out, on closer examination, to constitute provider protection. Id. at 223 n.5.

42. In one survey, "job lock" was understood by respondents to include such things as whether a potential employer offered coverage, whether that coverage was comparable to that offered by the current employer, and whether the insurance was affordable. See EMPLOYEE BENEFIT RES. INST., HEALTH INSURANCE PORTABILITY AND JOB LOCK: FINDINGS FROM THE 1998 HEALTH CONFIDENCE SURVEY, 19 EBRI NOTES NO. 8 (1998). To be sure, the absolute magnitude of such "job lock" is considerably less than is commonly believed. See Mark Pauly, Regulations Against Bad Things That Almost Never Happen, But Could: HIPPA and the Individual Insurance Market, 22 CATO J. (forthcoming 2002).

43. For example, if one's current

employer covered fertility treatments and a prospective employer did not (or imposed substantial waiting periods) and one were in the middle of a series of expensive fertility treatments, it is unlikely that one would be willing to change jobs. However, viewed from another perspective, this is simply a consequence of the fact that coverage terms vary among employers, and such variation can cause adverse selection, as employees on the margin select employers whose coverage best matches their preferences. Stated differently, in a competitive labor market, employers compete for employees by offering different mixes of wages and coverage. It is hard to come up with a coherent argument why competition for employees should be limited only to variations in wages, and coverage should converge on some Platonic ideal, unless one is prepared to imbed that preferred outcome in the beginning assumptions. See David F. Levi, In Memoriam Philip B. Kurland, 64 U. CHI. L. REV. 1, 4 (1997) ("The key to establishment of an infallible argument has been most fully developed by the Supreme Court of the United States: it is to embed the conclusion in the premise. It is always easier to get from here to here than to get from here to there.").

44. See Interview by PBS with Uwe Reinhardt, Professor, Princeton University at http://www.pbs.org/healthcarecrisis/Exprts _intrw/u_reinhardt.htm (suggesting that "the devil systematically built our health insurance system [which] has the feature that when you're down on your luck, you're unemployed, you lose your insurance.... Only the devil could ever have invented such a system. Humans of goodwill would never do this.").

45. Health Insurance Portability and Accountability Act, Pub. L. 104-191, 110

Stat. 1936 (1996); 29 U.S.C. § 1161 (1994); David L. Gregory, COBRA: Congress Provides Partial Protection Against Employer Termination of Retiree Health Insurance, 24 SAN DIEGO L. REV. 77 (1987); Thomas Somers, COBRA: An Incremental Approach to National Health Insurance, 5 J. CONTEMP. HEALTH L. & POL'Y. 141 (1989).

46. See Peter J. Cunningham & Paul B. Ginsburg, What Accounts for Differences in Uninsurance Rates Across Communities?, 38 INQUIRY 6 (2001). In particular, the southern and western United States have substantially higher rates of uninsurance.

47. Because the points in this paragraph have been covered extensively elsewhere and are already well understood by those familiar with health care law and policy, we provide only a short summary. For additional background discussion of insurance regulation and ERISA pregenerally Anne emption, see Mary Bobinski, Unhealthy Federalism: Barriers to Health Care Access Increasing for the Uninsured, 24 U.C. DAVIS L. REV. 255 (1990); Jesselyn Alicia Brown, ERISA and State Health Care Reform: Roadblock or Scapegoat?, 13 YALE L. & POL'Y REV. 339 (1995); Catherine Fisk, The Last Article about the Language of ERISA Preemption? A Case Study of the Failure of Textualism, 33 HARV. J. ON LEGIS. 35 (1996); and Jana K. Strain & Eleanor D. Kinney, The Road Paved with Good Intentions: Problems and Potential for Employer-Sponsored Health Insurance Under ERISA, 31 LOY. U. CHI. L.J. 29 (1999).

48. 29 U.S.C. § 1144 (1994); see also Daniel Fox & Daniel Schaffer, Health Policy and ERISA: Interest Groups and Semiprotection, 14 J. HEALTH POL., POL'Y & L. 239 (1989); Leon Irish & Harrison Cohen, ERISA Preemption: Judicial Flexibility and Statutory Rigidity, 19 U. MICH. J.L. REFORM 109, 111 (1985). 49. See David A. Hyman, Accountable Managed Care: Should We Be Careful What We Wish For? 32 U. MICH. J.L. REFORM 785 (1999) (providing a similar analysis for liability rights against MCOs). Whether traditional forms of accountability have actually ensured the delivery of high quality care is, of course, another matter entirely. See David A. Hyman & Charles Silver, Just What the Patient Ordered: Result Based Compensation for Health Care, WASH. & LEE L. REV. (forthcoming 2001) (detailing highly variable quality of American medical care, and proposing the use of explicit financial incentives to deliver high quality care).

50. See CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, EVIDENCE § 655 (1999) ("If the calling party's opponents cannot subject the witness to crossexamination for reasons that are not his fault, some remedy is necessary.... If crossexamination is permanently blocked, the direct testimony usually should be stricken in both civil and criminal cases, or a mistrial declared if the direct testimony is critical and striking it would not be effective.").

51. See KOMESAR, supra note 8, at 204. Our comparative institutional analysis considers the benefits of existing arrangements against the major competing alternatives. Not all of our critiques apply to all of the alternatives, so it is important for the reader to be clear about the frame of reference associated with any given critique.

52. See EMPLOYEE BENEFIT RES. INST., EMPLOYMENT-BASED HEALTH INSURANCE: A LOOK AT TAX ISSUES AND PUBLIC OPINION, ISSUE BRIEF NO. 211 (July, 1999), available at http://www.ebri.org/ ibex/ib211.htm ("A recent public opinion survey conducted by the Employee Benefit Research Institute found that 68 percent of Americans with employment-based health insurance were satisfied with the current mix of benefits and wages."); Lave et al., supra note 38, at 112; John R. Moran et al., Preference Diversity and the Breadth of Employee Health Insurance Options, 36 HEALTH SERVICES RES. 911 (2001); Pamela B. Peele et al., Employer-Sponsored Health Insurance: Are Employers Good Agents for their Employees?, 78 MILBANK Q. 5 (2000).

53. Hyman, supra note 4, at 235.

54. See James Maxwell et al., Corporate Health Care Purchasing Among Fortune 500 Firms, 20 HEALTH AFF., May-June 2001, at 181.

55. Mark A. Hall, The Geography of Health Insurance Regulation: A Guide to Identifying, Exploiting, and Policing Market Boundaries, 19 HEALTH AFF., Mar.-Apr. 2000, at 173.

56. To be sure, more comprehensive coverage is a double-edged sword, because it worsens the problem of moral hazard. Moral hazard is the tendency of insurance to increase the risk that is insured against, and the damages that result from the materialization of that risk. For a classic example, recounted in the form of a joke, see Marc Galanter, The Conniving Claimant: Changing Images of Misuse of Legal Remedies, 50 DEPAUL L. REV. 647, 657 (2000) ("A lawyer and an engineer were fishing in the Caribbean. The lawyer said, 'I am here because my house burned down and everything I owned was destroyed. The insurance company paid for everything.' 'That is quite a coincidence,' said the engineer, 'I'm here because my house and all my belongings were destroyed by a flood, and my insurance company also paid for everything.' The lawyer looked somewhat confused and asked, 'How do you start a flood?"). In the health care context, a person with insurance is more likely to consume more health care services when illness strikes. See Mark Pauly, The Economics of Moral Hazard, 58 AM. ECON. REV. 531, 535 (1968) ("[T]he response of seeking more medical care with insurance than in its absence is a result not of moral perfidy, but of rational economic behavior."). This fact explains why, from an economic perspective, comprehensive coverage is not socially optimal. Much of the fundamental structure of insurance policies can be explained by the need to control moral hazard. With traditional (indemnity) health insurance, co-payments and deductibles were employed to limit voluntary increases in the size of the covered loss. Many forms of managed care relied on non-financial barriers to treatment to accomplish the same result. When a policy must be renewed annually, moral hazard is also deterred by setting the premium on the basis of past loss experience. Finally, loss prevention strategies (e.g., wellness programs) can play a role as well. See EMPLOYEE BENEFIT RES. INST.. EMPLOYMENT-BASED HEALTH **PROMOTION AND WELLNESS PROGRAMS, 22** EBRI NOTES NO. 7 (2001).

57. The following discussion is based on MARK A. HALL, REFORMING PRIVATE HEALTH INSURANCE (1994). An additional source of adverse selection arises when the insurer is prohibited from using such information pursuant to state or federal law. Thus, anti-discrimination laws aimed at insurance coverage markets can actually create a potent source of discrimination, when compared to a risk-based market baseline.

58. This cost savings is independent of the tax advantages that accrue from employment-based coverage.

59. There is some evidence to suggest that employee wages are adjusted to reflect

the costs of coverage. See Blumberg, supra note 40, at 58-59. Obviously, the size of the cross-subsidies will be smaller to the extent that wages are adjusted for their existence. However, it appears that wages are adjusted on a demographic class basis, rather than on an individual basis, so there will still be some degree of cross-subsidization. See id.

60. William S. Custer et al., Why We Should Keep the Employment-Based Health Insurance System, 18 HEALTH AFF., Nov.-Dec. 1999, at 115.

61. See, e.g., THEDA SKOCPOL, BOOMERANG: HEALTH CARE REFORM AND THE TURN AGAINST GOVERNMENT (1999). Similar difficulties have beset efforts to adopt parity for mental health coverage, and community rating. See Daniel P. Gitterman et al., Toward Full Mental Health Parity and Beyond, 20 HEALTH AFF., July-Aug. 2001, at 68; HALL, supra note 57, at 38-43.

62. See HALL, supra note 34, at ch. 3; James F. Blumstein & Michael Zubkoff, Public Choice in Health: Problems, Politics and Perspectives on Formulating National Health Policy, 4 J. HEALTH POL., POL'Y & L. 382, 389-90 (1979) ("Decentralized choices by decisionmakers...has nongovernmental greater potential for precluding symbolic becoming concerns from inextricably involved in policy formulation and will likely point more attention to necessary economic tradeoffs. The design of institutions and policies should therefore take into account the 'susceptibility to symbolic blackmail' of governmental institutions when health issues are directly implicated."); Richard Epstein, Living Dangerously: A Defense of Mortal Peril, 1998 U. ILL. L. REV. 909, 927 ("[B]efore embarking down the road to [regulation], one has to make some estimate of the relative chances of success or failure, given the danger of regulatory capture and excess that can subvert a legislative program from any direction.... Private markets are more resistant to these pressures because exit and entry possibilities keep established players in line. State monopolies, on the other hand, can easily misbehave...."); Uwe E. Reinhardt, *Demagoguery and Debate over Medicare Reform*, 14 HEALTH AFF., Winter 1995, at 101, 103 ("One great advantage of cost and quality control through private regulators is that the latter are swift and usually not open to appeal.").

63. See Steven L. Schooner, Fear of Oversight: The Fundamental Failure of Businesslike Government, 50 AM. U. L. REV. 627 (2001); Joshua I. Schwartz, Liability For Sovereign Acts: Congruence and Exceptionalism in Government Contracts Law, 64 GEO. WASH. L. REV. 633 (1996).

64. See JACOB HACKER, THE ROAD TO NOWHERE 86 (1997) (noting "generic public distrust of government"); James A. Morone, The Bias of American Politics: Rationing Health Care in a Weak State, 140 U. PA. L. REV. 1923, 1924 (1992) ("Americans do not like government."). Indeed, for more than two decades, a clear majority of Americans have not believed the federal government is likely to "do what is right." See Robert J. Blendon & John M. Benson, American's Views on Health Policy: A Fifty-Year Historical Perspective, 20 HEALTH AFF., Mar.-Apr. 2001, at 33, 42. It remains to be seen whether these figures will remain as high in light of the events of September 11, 2001. See Richard Morin, Poll: National Confidence, Pride Soar, WASH. POST, Oct. 25, 2001, at A7 (noting survey indicating that 64% of Americans trusted the government to do the right thing most of the time or just about all the time, the highest figure since the poll began in 1966).

65. These programs came about because of a relatively unique combination

of circumstances, and did not represent a blanket repudiation of traditional American attitudes regarding governmental programs. See THEODORE E. MARMOR, THE POLITICS OF MEDICARE 126-27 (2d ed. 2000) ("A consensus on the seriousness of American medical care problems did not signify agreement on the shape, magnitude, or priority of those problems.... In fact, the more complex the problem, like making medical care accessible to and affordable for all Americans, the less likely that such an agreement can be forged, despite widespread agreement that the situation needs fixing.").

66. Even proponents of a single-payor system recognize that this is a "real issue and not just a rhetorical challenge." GORDON SCHIFF & DAVID HIMMELSTEIN, PHYSICIANS FOR A NATIONAL HEALTH PROGRAM, OUESTIONS AND ANSWERS ABOUT SINGLE PAYER NATIONAL HEALTH INSURANCE, (May 19, 1996), at http:// www.pnhp.org/basicinfo/qa2.html ("Would you really turn 15% of our economy over to government with the efficiency of the post office, the compassion of the IRS, and the cost effectiveness of the defense department?").

67. See CENTER FOR STUDYING HEALTH SYSTEM CHANGE, DEFINED CONTRIBUTIONS: THE SEARCH FOR A NEW VISION, ISSUE BRIEF NO. 37 (Apr. 2001), available at http://www.hschange.org/CONTENT/310; EMPLOYEE BENEFIT RES. INST., DEFINED CONTRIBUTION HEALTH BENEFITS, ISSUE BRIEF NO. 231 (Mar. 2001), available at http://www.ebri.org/ibex/ib231.htm; Julie Appleby, Benefits Firms Await Health Care Shift, USA TODAY, July 27, 2000, at B3; Greg Scandlen. Defined Contribution Health Insurance (National Center for Policy Analysis, Oct. 2000), available пt

http://www.ncpa.org/bg/bg154/bg154.html.

68. See Ron Winslow & Carl Gentry, Health-Benefits Trend: Give Workers Money, Let Them Buy a Plan, WALL ST. J., Feb. 8, 2000, at A1; http://www.ehealth insurance.com; see also Arti K. Rai,, Reflective Choice in Health Care: Using Information Technology to Present Allocation Options, 25 AM. J. L. & MED. 387 (1999) (noting the advantages of such technology in allowing employees to make their own cost/quality/benefit trade-offs).

69. See DAVID DRANOVE, THE EVOLUTION OF MEDICAL CARE: FROM MARCUS WELBY TO MANAGED CARE 143 (2000) ("Yet even when evidence emerges to indicate that some providers have below-average quality, most patients pretend they are some kind of 'Lake Wobegone' of medical care, where 'all of the providers are above average.'"); Blendon & Benson, *supra* note 64, at 41 ("[M]ore than 80 percent of Americans have reported that they are satisfied with their last visit to a physician.").

70. See Thomas Bodenheimer, The American Health Care System—The Movement for Improved Quality in Health Care, 340 NEW ENG. J. MED. 488 (1999); Mark R. Chassin, Is Health Care Ready for Six Sigma Quality?, 76 MILBANK Q. 565, 566 (1998); Mark A. Schuster et al., How Good Is the Quality of Health Care in the United States?, 76 MILBANK Q. 517 (1998).

71. See INSTITUTE OF MEDICINE, TO ERR IS HUMAN 22 (1999). These figures have been controversial; researchers have argued that many of the patients would have died anyway, or that reviewer assessments are unreliable. Rodney A. Hayward & Timothy P. Hofer, Estimating Hospital Deaths Due to Medical Errors: Preventability is in the Eye of the Reviewer, 286 JAMA 415 (2001); Christopher M. Hughes et al., Deaths Due to Medical Errors are Exaggerated in Institute of Medicine Report, 284 JAMA 93 (2000). Those involved in the preparation of the Institute of Medicine report have defended these figures. Lucian Leape, Institute of Medicine Medical Error Figures are not Exaggerated, 284 JAMA 95 (2000).

72. See INSTITUTE OF MEDICINE, supra note 71, at 1.

73. See ALPHA CENTER, PURCHASING PATHFINDERS (2001) (describing efforts of employers to "buy-right"); JACK MEYER ET AL., AGENCY FOR HEALTH CARE POL'Y RES. PUB. NO. 98-0004, THEORY AND REALITY OF VALUE-BASED PURCHASING, (Nov. 1997), at http://www.ahrq.gov/qual/meyerrpt.htm

(describing the few employers who are using financial incentives and other techniques to improve health care for employees as "pioneers"); Helen Halpin Schauffler et al., *Raising The Bar: The Use of Performance Guarantees by the Pacific Business Group on Health*, 18 HEALTH AFF., Mar.-Apr. 1999, at 134.

74. See R. Adams Dudley et al., The Impact of Financial Incentives on Quality of Health Care, 76 MILBANK Q. 649, 654 (1998); Fred J. Hellinger, The Impact of Financial Incentives on Physician Behavior in Managed Care Plans: A Review of the Evidence, 53 MED. CARE. RES. & REV. 294 (1996); Alan L. Hillman et al., How Do Financial Incentives Affect Physicians Clinical Decisions and The Financial Performance of Health Maintenance Organizations? 321 NEW ENG. J. MED. 86 (1989); James C. Robinson, Theory and Practice in the Design of Physician Payment Incentives, 79 MILBANK Q. 149 (2001).

75. The measures included the number of pregnant women who received prenatal care during the first trimester, mammography, Pap smears, childhood immunizations, diabetic retinal exam, and cesarean sections. *See* Schauffler et al., *supra* note 73, at 135. 76. Id. at 137-38.

77. See, e.g., Bodenheimer & Sullivan, supra note 39, at 1005-07 (Minnesota Buyers Health Care Action Group); Linda O. Prager, *Coalition Proposes Pay Based on Quality*, 43 AM. MED. NEWS, June 19, 2000, at 8; Massachusetts Health Care Purchasers Group, *available at* http://www.mhpg.org/ (last visited Oct. 31, 2001).

78. See THE LEAPFROG GROUP, PATIENT SAFETY, at http://www.leapfroggroup.org/ safety1.htm (last visited Oct. 31, 2001).

79. See THE LEAPFROG GROUP, ECONOMIC IMPLICATIONS OF THE LEAPFROG PATIENT SAFETY STANDARDS (John D. Birkmeyer ed., June 2001), available at http://www.leapfroggroup.org/toolkit/LF. Costs.Final.pdf.

80. But see M. Susan Marquis & Stephen H. Long, Prevalence Of Selected Employer Health Insurance Purchasing Strategies in 1997, 20 HEALTH AFF., July-Aug. 2001, at 220 (presenting data indicating many employers are using quality information in choosing which health plans to offer).

81. See supra note 62.

82. See MICHAEL L. MILLENSON, DEMANDING MEDICAL EXCELLENCE 196 (1997). The proposal is described in greater detail in Sarah Lyall, Proposal Ties Hospital Reimbursement to the Quality of Care, N.Y. TIMES, Dec. 25, 1992, at B1.

83. See AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS, HCFA ANNOUNCES DEMONSTRATION PROJECT FOR OINT REPLACEMENT SURGERY, (May 1996) at http://www.aaos.org/wordhtml/wash_rep/ (criticizing Centers hcfa0596.htm of Excellence Initiative for focusing on cost instead of quality); HEALTH CARE FINANCING ADMINISTRATION, FREQUENTLY ASKED OUESTIONS, at http://www.hcfa. gov/research/qpappfaq.htm (last visited Dec. 9, 2001) (outlining Centers of Excellence demonstration project).

84. LESLIE A. JACKSON & SALLY TRUDE, CENTER FOR STUDYING HEALTH SYSTEM CHANGE, STAND-ALONE HEALTH INSURANCE TAX CREDITS AREN'T ENOUGH, ISSUE BRIEF NO. 41 (July 2001), available at http://www.hschange.org/CONTENT/347; Katherine Swartz, Markets for Individual Health Insurance: Can we Make them Work with Incentives to Purchase Insurance?, 38 INQUIRY 133 (2001).

85. Karen Pollitz, How Accessible is Individual Health Insurance for Consumers in Less-than-Perfect Health? (Henry J. Kaiser Family Foundation, June 2001); see also Elisabeth Simantov et al., Market Failure? Individual Insurance Markets For Older Americans, 19 HEALTH AFF., July-Aug. 2001, at 139.

86. See Hyman, supra note 4, at 246-53, 259-63.

87. Hall, supra note 55, at 178-79.

88. Mark A. Hall, An Evaluation of New York's Health Insurance Reform Law, 25 J. HEALTH POL., POL'Y & L. 71 (2000).

89. See Mark A. Hall et al., HealthMarts, HIPCs, MEWAs, and Association Health Plans (AHPs): A Guide for the Perplexed, 20 HEALTH AFF., Jan.-Feb. 2001, at 142.

90. Elliot Wicks & Mark A. Hall, Purchasing Cooperatives for Small Employers: Performance and Prospects, 78 MILBANK Q. 511 (2000).

91. Robert Kuttner, *The Risk-Adjustment* Debate, 339 NEW ENG. J. MED. 1952 (1998).

92. See Hyman, supra note 4, at 246-53, 259-63.

93. The range of possible outcomes is neatly demonstrated by the differing financial status of the Medicare and Medicaid programs—with the latter varying tremendously from state to state.

94. One recent example of this phenomena is that low Medicare

reimbursement for mammography has resulted in a shortage of providers and lengthy waiting periods for those who wish to obtain such screening. See M. William Salganik, Breast-Test Centers Decline as Need for Them Increases, BALT. SUN, Oct. 28, 2001, at 1C; Judy Muller, Fatal Wait: Women Have Trouble Finding Doctors To Provide Mammograms, abcNEWS.com, Aug. 23. 2001, at http://abcnews.go.com/sections /wnt/WorldNewsTonight/mammogram01 0823.html. This problem will become even more acute if Medicare succeeds in raising the number of beneficiaries who receive recommended mammography screening from its current low level. See CENTER FOR MEDICARE & MEDICAID SERVICES, OUALITY OF CARE-PRO PRIORITIES, at http:// www.hcfa.gov/quality/11a2-c.htm (describing breast cancer initiative, to address the fact that only "30 to 60 percent of women over age 50 undergo routine mammography," and a substantial proportion have never had a mammogram). Similar risks are associated with monopsony purchasing in the pharmaceutical market, as the desire to obtain low prices for today's beneficiaries is at war with the importance of ensuring adequate funds are available for research to develop next year's treatments.

95. NICCOLO MACHIAVELLI, THE PRINCE 17(Robert M. Adams ed. & trans., Norton Press 1977)(1513).

96. See Morone, supra note 64, at 1928.

97. HACKER, supra note 64; Lawrence D. Brown, Who Shall Pay? Politics, Money, And Health Care Reform, 13 HEALTH AFF., Spring 1994, at 175.

98. See ECONOMIC AND SOC. RES. INST., COVERING AMERICA: REAL REMEDIES FOR THE UNINSURED (Elliot K. Wicks ed., June 2001), available at http://www. esresearch.org/RWJ11PDF/summary.pdf; Judith Feder et al., Covering the Low-Income Uninsured: The Case for Expanding Public Programs, 20 HEALTH AFF., Jan.-Feb. 2001, at 27 ("Any initiative to extend health insurance to the forty-three million Americans without it is likely to take an incremental strategy rather than a universal comprehensive or approach."); Symposium, Strategies to Expand Health Insurance for Working Americans, 38 INQUIRY 90 (2001).

99. A more Machiavellian interpretation is that incremental reforms are focused on appeasing the interests of the middle and upper classes, and thus fragment the coalition that would otherwise bring about more sweeping reforms. This argument is consistent with the fact not that incremental reforms have been proposed by both Democrats and Republicans. More to the point, it is hardly a dispositive indictment of a policy reform that it does everything simultaneously. not solve Indeed, the economic and social upheaval that would appear necessary to produce truly comprehensive reform of the entire health care delivery system is sufficiently sweeping that comprehensive reform has found virtually no takers since the demise of the Clinton plan. Regardless, the reforms we propose include both the "haves" (i.e., people with insurance) and the "have nots." Unless one is inclined toward a Marxist view that such reforms should be shunned precisely because they the necessary widespread undermine misery to bring about global reform, it is hard to justify opposition to incremental reform as such.

100. See, e.g., Arnett, supra note 3 (collecting various papers on the subject); Butler & Kendall, supra note 3; Lynn Etheredge, A Flexible Benefits Tax Credit for Health Insurance and More, 20 HEALTH AFF., May-June 2001, at 8; Mark V. Pauly & John Goodman, Tax Credits for Health Insurance and Medical Savings Accounts, 14 HEALTH AFF., Spring 1995, at 125. Strictly speaking, it would be preferable from an economic perspective to "fix" the tax subsidy by eliminating it but the political dynamics make that an extremely unlikely outcome. See Hyman, supra note 4, at 274 (listing market-enhancing regulatory strategies, including "the leveling (preferably down, but likely up) the more of tax purchasing health consequences of insurance through employer and nonemployer-based markets.") Tax credits are preferable to tax deductions because their value is not affected by one's tax bracket; they can be made refundable; and they are not contingent on whether one itemizes.

101. Government programs, such as Medicare, can also be converted into voucher programs so that individual beneficiaries can purchase private coverage. However, given the complexity of this issue, we limit our analysis to the use of tax credits for those not covered by governmental programs.

102. See New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). One intriguing possibility is to move insurance regulation toward a corporate law model. Employers and insurers could be required to subject themselves to the laws and regulations of a single state, but allowed to select the state. As with corporate charters, this system would create a market for regulatory oversight, and would allow employers and insurers to select the regulatory regime that functioned most efficiently and cost-

needs effectively matched the and preferences of their risk pool(s). The ability of employers and insurers to exit from the state's regulatory oversight (taking their premium taxes with them) would temper opportunistic behavior by legislators and regulators. A race to the bottom would be unlikely because the state's residents would be the first to be affected. See Christopher C. DeMuth, Why The Era of Big Government Isn't Over, 109 COMMENTARY, Apr. 2000, at 23, 29; Tom Miller, A Regulatory Bypass Operation, 22 CATO J. (forthcoming 2002).

103. See Hyman, supra note 49, at 810.

104. To be sure, employee calculations of risk are subject to an array of biases, and are likely to be influenced by the perceived availability of "safety-net" providers, who will take care of them without regard to ability to pay. See Korobkin, supra note 35, at 48-60; Bradley J. Herring, Does Access to Charity Care For the Uninsured Crowd Out Private Health Insurance Coverage? (unpublished manuscript on file with authors).

105. Mark Pauly, Trading Cost, Quality, and Coverage of the Uninsured: What Will We Demand and What Will We Supply?, in THE FUTURE U.S. HEALTHCARE SYSTEM: WHO WILL CARE FOR THE POOR AND UNINSURED? 364 (Stuart Altman et al. eds., 1998). One influential commentator has suggested that this failure has come about "not because Americans are unusually callous toward the poor, but in part because the American health system has priced kindness out of the nation's soul." Reinhardt, supra note 5, at 327. However, it is unclear the extent to which these revealed preferences are pricesensitive.

106. In this regard, employment-based insurance may be a true example of a path-dependent institutional arrangement. See

generally Oona A. Hathaway, The Path Dependence of the Law: The Course and Pattern of Legal Change in a Common Law System, 86 IOWA L. REV. 601 (2001). But see Hyman, supra note 4, at 270 n.157 ("First, it is easier to articulate a theory of path dependence than it is to find empirical evidence of the phenomenon in the health care marketplace, let alone evidence that it can be fixed without inducing worse distortions. Second. the tumultuous restructuring of the health care economy in the past decade away from fee-for-service and toward managed care suggests that there are no real impediments to further restructuring-except those created by well-meaning legislators, that is. Finally, if medicine were really beset by path dependence, we would still be bleeding people for fevers.").

107. Russell Korobkin, The Status Quo Bias And Contract Default Rules, 83 CORNELL L. REV. 608 (1998).

108. EMPLOYEE BENEFIT RES. INST., RETIREE HEALTH BENEFITS: WHAT THE CHANGES MAY MEAN FOR FUTURE BENEFITS, ISSUE BRIEF NO. 175 (July 1996), available at http://www.ebri.org/ ibex/ib175.htm.

109. David M. Studdert et al., Expanded Managed Care Liability: What Impact on Employer Coverage?, 18 HEALTH AFF., Nov-Dec. 1999, at 7, 20-22 (modeling impact of liability on employer participation in coverage market); Marsha Austin, Patients' Bill May Spur Firms to End Benefits, DENVER POST, Aug. 8, 2001, at C-01.

110. See supra note 52.

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Medical Standard of Care Jurisprudence as Evolutionary Process: Implications Under Managed Care

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Medical malpractice lawsuits are by far the most numerous of the professional negligence cases.¹ Accordingly, the health care community may serve as a paradigm for professional standards of care.² But in the era of "managed health care,"³ does modern medical practice truly comport with the long standing tradition of a professional standard of care privilege? This Article explores the jurisprudential evolution of this standard and endeavors to conceptualize the potential impact of managed care.

In an ordinary negligence case, a jury may find for the plaintiff by concluding that the defendant's conduct fell below a "reasonable man" standard.⁴ Direct evidence of compliance (or lack thereof) with a given standard of care is not ordinarily considered.⁵ The jury merely weighs a given risk against the utility of conduct, which either increases or lessens that risk.⁶ In addition, outside opinions need not impact the jury—the jury applies community standards in drawing upon its collective experience to reach a verdict.⁷

This reasonableness standard does not apply to professionals, such as doctors, lawyers, and accountants.⁸ Professionals must not only "exercise reasonable care in what they do, but [must also] possess a minimum amount of special knowledge and ability."⁹ The jury is usually instructed to consider "the skill and learning commonly possessed by members of a profession in good standing."¹⁰ In professional malpractice cases, it thus considers the standard of "what is customary and usual in a profession."¹¹ This gives the court-recognized professions, most notably the medical profession, the privilege of setting its own standards of practice.¹²

In Rossell v. Volkswagen of America,¹³ the court found that a defendant car manufacturer was not entitled to a professional standard of care in a

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product design liability case.¹⁴ In support of its position, the court sets forth a logistical construct to separate professional malpractice cases from "commercial cases:"

The malpractice requirement that plaintiff show the details of conduct practiced by others in defendant's profession is not some special favor which the law gives to professionals who may be sued by their clients. It is, instead, a method of holding such defendants to an even higher standard of care than that of an ordinary, prudent person.... Such a technique has not been applied in commercial settings, probably because the danger of allowing a commercial group to set its own standard of what is reasonable is not offset by professional obligations which tend to prevent the group from setting standards at a low level in order to accommodate other interests. Thus, it is the general law that industries are not permitted to establish their own standard of conduct because they may be influenced by motives of saving 'time, efforts or money.'¹⁵

The *Rossell* opinion was written in 1985.¹⁶ Reconsidered in the context of 2002 managed realities, one wonders if our present court system romanticizes the professions in rationalizing a higher, privileged standard of care. Is it not true that business interests heavily influence most modern professions, including health care? If so, is the jurisprudential construct for a "medical professional standard" an anachronism in today's world (hence ripe for change)?

I. COMMON LAW ORIGINS OF A MEDICAL STANDARD OF CARE

Under the legal system of medieval England, plaintiffs required an official form of action from the royal court (a "writ") that pertained to particular classes of cases.¹⁷ Prior to the fourteenth century, actionable court complaints were generally based on the writ of trespass, or a variant thereof (e.g., "trespass to the person, to land, or to goods"¹⁸). There was originally no distinction between contract law and tort law.¹⁹ Hence, professional malpractice cases often displayed tension between "breach of covenant" (contract law) and "writ of trespass" against the person or case (tort law).²⁰

The 1300s saw the development of what Professor Prosser described as "the borderland of tort and contract," specifically involving those persons practicing their professional trade or "calling."²¹ In *The Oculist's Case*²² of 1329, the plaintiff's counsel argued for a breach of covenant action against a physician who failed to keep a promise to successfully treat the plaintiff's eye disease.²³ The presiding Justice ultimately rejected the contract law approach.²⁴ Instead, he linked the concept of "profession" with "man of

skill," comparing medical healers to farriers who negligently injured horses while shoeing.²⁵ By both tradition and law, one could not (at that time) recover against the farrier; hence, he reasoned, one could not recover against a physician.²⁶

Although the early professional malpractice cases alleged violation of an "assumpsit,"²⁷ the courts generally found action based on "trespass on the case."²⁸ Those professionals serving the public-at-large (often described as engaged in a "calling") were thus held liable under pure tort theory, with breach of covenant merely incidental to the alleged injury.²⁹ Accordingly, in *Tailboys v. Sherman* (1443),³⁰ the presiding justice in a professional negligence case suggests a writ of trespass may arise from a breach of covenant.³¹

The professional standard of care percolated through the socio-legal evolutionary changes of the fourteenth, fifteenth, and sixteenth centuries, when medieval societies were stratified.³² Different professions enjoyed variable degrees of legal status.³³ Prior to the Black Plague of the 1300s, historians note an apparent "absolute" occupational privilege enjoyed by physicians, protecting them against any liability for negligent injury or death.³⁴ Although not codified, this privilege was defined by absence of regulations and hence lack of standards.³⁵ Although medieval England had instituted some urban social regulation by that time, such regulations did not extend to the practice of medicine.³⁶

Seen in the light of physicians' privilege, plaintiffs' attempts to sue under breach of assumpsit may be viewed as clever attempts to bypass judiciary reluctance to hold physicians accountable for negligence. Unfortunately, patients generally failed to obtain written agreements before treatment, which would have been necessary for successful contract litigation.³⁷

Doctors' absolute privilege ended about the same time the chancery's role in issuing writs increased.³⁸ However, some chancellors continued to refuse all writs against doctors, apparently under influence from particular justices on the King's Bench.³⁹ Public health policy concerns likely affected these views.⁴⁰ But what of those doctors who refused to treat patients during the Plague? Although doctors refusing service were arguably liable for "nonfeasance" (not performing a required act), the great need for their services continued to supplant liability for "misfeasance" (performing an act improperly).⁴¹ Thus, the necessities created by a public health catastrophe granted physicians continued privilege against liability.

Since medical practice remained unregulated, courts grappled erratically with the concept of a "standard." In *Stratten v. Swanland* (1374),⁴² a medieval case alleging that the plaintiff's hand was maimed by the

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surgeon's negligence, the standard appears to be based on moral fault (e.g., "he tried with due diligence, therefore should not be held guilty"⁴³). There is no discussion of any breached standard of care.⁴⁴ Then, in *Skyrne* v. *Butolf*,⁴⁵ another fourteenth-century case alleging the failure of a physician to keep his promise to cure a patient's disease, the court discussed the practitioner's actions as contrary to a generally held standard.⁴⁶ This is done in the context of deciding the issue of action based on writ of trespass versus breach of covenant.⁴⁷ The court suggests writ of trespass requires definition of a local standard, whereas a suit based on contract law does not.⁴⁸

By the early 1400s, nonfeasance had become the underlying basis for contract law disputes, while misfeasance remained the basis for action in tort.⁴⁹ But English tort law development subsequently produced a dichotomy—"action upon the case for misfeasance," versus "action upon the case for negligence."⁵⁰ This split was arguably crucial to the synthesis of a professional standard of care construct.⁵¹ According to Sir John Cromyn's *Digest of the Laws of England* (1740),⁵² "action upon the case for misfeasance" pertained to "misadventure."⁵³ It generally did not apply to skilled professionals, appearing closer to relying on our modern "reasonable man" standard of negligence.⁵⁴ By contrast, "action upon the case for negligence" pertained to breach of duties "imposed by law," "imposed by an office," or based upon "customs of the realm," thus seemingly applicable to the professions.⁵⁵

From where did this dichotomy arise? The English courts vacillated between the search for breach of a professional standard, versus evaluation of each individual defendant's skill (as noted in the "moral fault" approach).⁵⁶ Moral fault was arguably easier to adjudicate in an era when standards of knowledge remained ill defined. In the absence of this knowledge, professional negligence based on deviation from a standard could best be defined as deviation from a legally imposed regulatory standard, of which there were few.⁵⁷ Thus the concept of professional standards evolved in concurrence with subsequent government-imposed regulations.⁵⁸ The English aristocracy's desire for skilled professions to serve the public-at-large may have engendered considerable leeway and privilege in the development of these standards, including acquiescence to "custom of the realm."

It was within this context that King Henry VIII, in 1518, created by royal charter the Royal College of Physicians and Surgeons,⁶⁰ seemingly elevating the medical profession above all others in the professional standard of care paradigm. The main purpose of the Royal College, as defined by its Charter, included the granting of licenses to qualified practitioners and the punishment of unqualified practitioners, including those committing malpractice.⁶¹ Its reach extended to both physicians and apothecaries.⁶² Originally its jurisdiction was confined to London, but an Act of Parliament in 1523 extended the College's power to include all of England.⁶³

The Royal College established licensure methodology and requirements for English physicians and surgeons.⁶⁴ Ultimate authority rested in its "Board of Censors," consisting of the Bishop of London (or Dean of St. Paul), plus four physicians.⁶⁵ Licensure also required approval of a diocese bishop (particularly if a "foreigner" applied), or else a diploma from Oxford or Cambridge University.⁶⁶ The original charter also granted College member physicians an exemption from conscripted services, which were still common at that time (e.g., watchmen and constables).⁶⁷

The Board of Censors acted much as a present day American state medical board, albeit with enhanced power. It possessed judicial authority, and could thus fine or imprison those persons practicing outside of their regulations (e.g., a druggist sending medicine to a sick patient without a doctor's prescription).⁶⁸ They were even allowed to search apothecary shops to ensure no "faulty drugs."⁶⁹ Board members thus held a status on par with judges. Hence the medical profession of that time was entrusted with power to police itself, arguably a reflection of special social status.

The Royal Charter allowed physicians to regulate themselves through self-imposed standards.⁷⁰ Yet the Charter itself alludes to a standard of care only once: "Where any person is condemned by the censors for not well executing, practicing, or using the faculty of physick, he may within fourteen days after notice appeal to the College, and the judgment given on such an appeal shall be final."⁷¹ Further definition of this standard thus lay within the College's discretion.

Review of Victorian era case digests reveals a distinct paucity of recorded medical malpractice cases. *Laws of England* (1920), describing case law through the 1800s, suggests negligence actions against physicians were "rarely successful."⁷² There were occasional exceptions. A surgeon was held "liable for ignorance and lack of skill" in *Slater v. Baker.*⁷⁸ Later, *Seare v. Prentice*,⁷⁴ stated: "[E]very one who undertakes any office, employment, trust or duty...to perform it with integrity, diligence and skill...if by his want of either of these qualities any injury accrues to individuals, they have therefor [sic] their remedy in damages....,⁷⁵ Still debating contract theory, the court in *Pippin v. Shepard*,⁷⁶ wondered how contractual obligation could be applied to physicians employed by public establishments.⁷⁷ "[I]t could hardly be expected that the governors of an infirmary could bring an action against the surgeon employed by them to attend the child of poor

parents who may have suffered from his negligence and inattention."⁷⁸ The holding in *Gladwell v. Steggall*,⁷⁹ appears to clarify this point: "The substance of the issue...is that the defendant was employed to *cure* the plaintiff, not that he was employed *by* the plaintiff."⁸⁰

Physician malpractice cases did occur with greater frequency by the nineteenth century, but judicial holdings tended to favor "the learned professions."⁸¹ Thus, in *Lanphier v. Phipos*, ⁸² the court held that "reasonable skill," as applied to professionals, is "not [the] highest possible degree of skill."⁸⁵ Later, the decision in *Rich v. Pierpont*⁸⁴ set the bar even lower (for medical professionals) with an amorphous standard:

[T] here must have been a want of competent and ordinary care and skill, and to such a degree as to have led to a bad result. A medical man is bound to have that degree of skill which cannot be defined, but which, in the opinion of the jury, is a competent degree of skill and knowledge.⁸⁵

Many of these concepts were subsequently adopted by American jurisprudence.⁸⁶ Further refinement of the English standard of care construct did not occur until the late nineteenth century. Although Parliament's Medical Act of 1858 facilitated the public's attempts to distinguish between "qualified" and "unqualified" health practitioners, "qualified" was defined simply as compliance with licensure requirements.⁸⁷ Interestingly, the Act of 1858 did not bar unqualified practitioners from practicing.⁸⁸

The Medical Act of 1886 further codified the requirement for physicians to register with the Royal College, and set a standard of "infamous conduct" as sufficient grounds for removal.⁸⁹ English case law subsequently defined "infamous conduct" as "dishonorable and disgraceful behavior."⁹⁰ At the same time, cases continued to define the medical standard of care not as the best care, but rather as "ordinary" care.⁹¹

American jurisprudence is arguably a product of English common law's influence on the colonies, and subsequently on the fledgling United States. Even a century after independence, it was not uncommon for American legal texts to refer to the utility of English cases. Josiah Smith's *A Manual of Common Law* (1875), an American publication of English cases/legal theory, describes its own contents as "comprising the fundamental principles and the points most usually occurring in daily life and practice."⁹² Its sole reference to standard of care for medical malpractice displays an ambiguity true to its English origins: "gross unskillfulness or carelessness."⁹³

In discussing more recent developments in the English law of liability, Professor John Fleming had once noted: Among the various professional groups, medical men seem to be the most frequent target of tort litigation, and medical malpractice actions furnish a microcosm of prevailing community and courtroom attitudes towards the problem of professional liability. Since the end of [World War II], there has been a noticeable increase in the volume of such actions in England, though it has not nearly attained the proportions endemic in the United States.⁹⁴

II. MEDICAL STANDARD OF CARE IN AMERICAN CASE LAW

The earliest documented American physician malpractice case, Cross v. Guthery,⁹⁵ involved a charge of negligence in the performance of a mastectomy.⁹⁶ The court ruled against the physician, reasoning he had set out to perform "with skill and safety" yet did so "in the most unskillful, ignorant and cruel manner, contrary to all the well known rules and principles of practice in such cases."⁹⁷ Later, in *McCandless v. McWha*,⁹⁸ a court defined the standard of care as the physician's obligation "to treat the case with diligence and skill…such reasonable skill and diligence as are ordinarily exercised in [the] profession…such as thoroughly educated surgeons ordinarily employ."⁹⁹

A concurrent case, *Leighten v. Sargent*,¹⁰⁰ set forth a similar standard of reasonable skill, but added, "He does not undertake for extraordinary care or extraordinary diligence, any more than he does for uncommon skill...^{"101} Further, that court maintained a residual element of contract theory, stating: "In stipulating to exert his skill, and apply his diligence and care, the medical or other professional men contract to use their best judgment...^{"102} Although modern emphasis has since settled almost exclusively on negligence theory, the contractual underpinnings of the physician-patient relationship were never entirely abandoned,¹⁰³ and still form the basis of many present-day suits against managed care companies.¹⁰⁴

Although American case law provides variable formulations of the medical professional standard of care, the common elements have been summarized as follows: "(1) A reasonable or ordinary degree of skill and learning; (2) commonly possessed and exercised by members of the profession[;] (3) who are of the same school or system as the defendant[;] (4) and who practice in...similar localities; (5) and exercise of the defendant's good judgment."¹⁰⁵

Physicians who comply with such standards are generally shielded from liability, since compliance is held as evidence of proper care.¹⁰⁶ Doctors are thus better protected from liability as compared to, say,

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railroads, merchants, car manufacturers, and the like.¹⁰⁷ Business and industry, on the other hand, may be held liable for negligence even if a plaintiff fails to show any departure from business custom.¹⁰⁸ Then why are doctors protected? While some legal historians have argued that "doctors as a class may be more likely to exert their best efforts than drovers, railroads and merchants,"¹⁰⁹ others conclude that "no other standard is practical," given the difficulty faced by the courts in determining whether a physician exercised reasonable medical care.¹¹⁰ Plaintiffs must thus rely on expert medical testimony to prove a case.¹¹¹

The term "average" is sometimes used in conjunction with—or in place of—the term "ordinary" in reference to the standards.¹¹² In *Holtzman* v. Hoy,¹¹³ an American court interpreted such terms as referring to an ordinary "good" physician.¹¹⁴ However, courts retain leeway for jury instructions,¹¹⁵ and jurors may thus have variable understandings of these issues. Ordinary/average standards have been translated into "minimum standards" when applied to scientific realms. For example, in *Hazel v. Mullen*,¹¹⁶ a case involving adverse health consequences from an x-ray machine, the plaintiff was unsuccessful despite presenting expert testimony of additional precautionary measures that the defendant may have taken to protect the plaintiff from injury.¹¹⁷ The defendant had demonstrated compliance with a scientifically recognized standard, which relied in large part on the ordinary judgment of the treating physician.¹¹⁸

While expert medical testimony is usually indispensable for establishing a medical standard of care, there are exceptions. For example, such testimony is not required when a patient suffers burns from a hot compress post-operatively,¹¹⁹ or if a physician accidentally knocks a healthy tooth from a patient's mouth prior to surgery.¹²⁰ Exceptions apply in particular for lapses in care subject to "common knowledge."¹²¹ The common knowledge standard is applied (often in conjunction with the doctrine of *res ipsa loquitor*) most frequently in cases where foreign objects are left in patients' bodies during operations.¹²² To utilize such a standard, negligence must be "so grossly apparent that a layman would have no difficulty recognizing it."¹²³ Application of this rule varies by jurisdiction.¹²⁴

Plaintiffs have attempted to circumvent the professional standard of care when the line between "common knowledge" and "medical knowledge" is blurred. In *Stepakoff v. Kantor*,¹²⁵ a jury found for the defendant psychiatrist in a case alleging negligence for a patient's suicide.¹²⁶ Plaintiff appealed, claiming that although the psychiatrist may not have breached the ordinary medical standard of care, common sense dictated the need for additional measures, such as involuntary hospitalization, to protect against suicide.¹²⁷ The court affirmed the jury

verdict, holding the standard of care cannot be divided into medical standard on the one hand, and reasonableness standard on the other hand.¹²⁸ It distinguished its ruling from *Tarasoff v. Regents of the University of California*,¹²⁹ a case involving a psychiatrist's duty to protect a third party (not a patient) under a reasonable care (not a professional standard of care) analysis.¹³⁰

Physicians enjoy further protection from liability when they choose between providing two or more appropriate alternative medical treatments. In *Morlino v. Medical Center of Ocean County*,¹³¹ the court found that harm resulting from such a choice does not constitute malpractice, so long as the physician acted with good faith judgment.¹³² This axiom has, however, been subject to modification. *Matthies v. Mastromonaco*¹³³ clarified that the patient, not the physician, must ultimately choose, and the standard of care is breached if the physician fails to inform the patient of all alternative treatments.¹⁵⁴ These issues may be particularly relevant to lawsuits involving managed care/HMOs.

The first reported malpractice suit against a managed care company was Wickline v. State of California,¹³⁵ heard on appeal in 1986. In 1976, Wickline was diagnosed with Leriche's Syndrome, a condition causing blockage of her aortic artery.¹³⁶ She subsequently underwent major surgery in 1977 to alleviate the problem, using a synthetic graft artery.¹³⁷ She experienced major post-operative complications, including vascular spasms, which threatened to cut off blood flow to her legs and raised the specter of lower extremity amputation.¹³⁸ The treating physicians originally had approval from the patient's HMO (Medi-Cal) for a ten-day postoperative stay.¹³⁹ Due to the post-operative complications, her physicians, with assistance from the hospital case management staff, requested an additional eight days in the hospital.¹⁴⁰ Medi-Cal asked their employed-physician consultant to review the case.¹⁴¹ Although Medi-Cal's physician reviewer was not a vascular specialist, and although he never consulted such a specialist, nor ever saw or examined the patient himself, Medi-Cal adopted his recommendation that the patient did not require additional time in the hospital.¹⁴² Her physician thus discharged her home after the initial ten days.¹⁴³ Her right leg became progressively discolored at home, and she was re-hospitalized nine days later.¹⁴⁴ However, it was too late to save her leg, and she ultimately required an above-the-knee amputation.¹⁴⁵ Her physician later testified that she would not have lost her leg had she remained in the hospital as originally requested.¹⁴⁶ The trial court found for the plaintiff, holding Medi-Cal liable for the plaintiff's injuries, pain, and suffering.¹⁴⁷ On appeal, the court reversed, reasoning that the plaintiff's own physician adopted Medi-Cal's decision without sufficient protest, and was ultimately still responsible for the patient's care when he wrote the order to discharge her home.¹⁴⁸ The court indicated that the physician and hospital had alternative avenues to protect the patient's interest, such as filing a formal appeal with Medi-Cal, or attempting to contact the reviewing physician directly.¹⁴⁹ Hence, Medi-Cal was not liable for the decision to discharge the patient.¹⁵⁰ Further, although the Medi-Cal physician reviewer may not have optimally analyzed the data before him, both he and Medi-Cal purportedly followed pertinent legislated state statutes regarding case review.¹⁵¹ Thus, the court ruled, Medi-Cal was not liable as a matter of law.¹⁵²

But *Wickline* did not completely close the door on managed care liability. The court also stated that "a patient who requires treatment and who is harmed when care which should have been provided is not provided should recover for the injuries suffered from all those responsible for the deprivation of care, including, when appropriate, health care payers."¹⁵³ Thus, managed care entities may be liable when medically incorrect decisions result from flaws in their cost-containment mechanisms.

A subsequent case, *Wilson v. Blue Cross of Southern California*,¹⁵⁴ supported the concept of liability for HMOs and other insurers.¹⁵⁵ In *Wilson*, a psychiatric patient committed suicide after his premature discharge from the hospital.¹⁵⁶ A managed care company's utilization review purportedly pressured the health care providers to discharge him.¹⁵⁷ The insurer argued it was entitled to summary judgment "because there are important public policy considerations which warrant protecting insurance companies and related entities which conduct concurrent utilization review."¹⁵⁸ Unlike *Wickline*, the *Wilson* court noted that despite the physician's decision to discharge the patient, the insurer might also be held at least partially liable if its negligent conduct acted as a substantial factor in causing harm.¹⁵⁹ *Wilson* thus appears to allow a jurisprudential bifurcation between the physician's professional standard of care and an insurer's duty to act under a reasonable standard of conduct.¹⁶⁰

In *Fox v. Health Net*, the plaintiffs used contract theory to successfully sue an HMO that denied coverage for a bone marrow transplant to treat breast, cancer.¹⁶¹ The jury awarded \$77 million for punitive damages after finding breach of contract, intentional infliction of emotional distress "through reckless denial of coverage," and actions in bad faith.¹⁶² Under contract theory, there was no need to prove breach of a professional standard of care, only that there was a breach of a *contract* for care.¹⁶³

The employer sponsor of Health Net was a state public school district, hence not protected by the Employee Retirement Income Security Act

(ERISA).¹⁶⁴ ERISA¹⁶⁵ does not allow recovery of monetary damages due to an administrator's purported misconduct in the private sector.¹⁶⁶ This preemption is extended to those managed care health insurers sponsored by private employers.¹⁶⁷ Had the *Fox* case involved a private employer's health plan, the outcome may have been dramatically different. In *Durham v. Health Net*,¹⁶⁸ plaintiff's similar action against a restaurant for monetary damages under ERISA was dismissed.¹⁶⁹

In June 2000, the U.S. Supreme Court ruled "treatment decisions made by a health maintenance organization, acting through its physician employees," are not fiduciary decisions under ERISA.¹⁷⁰ The Court reasoned that Congress never intended to open "the federal courthouse doors for a fiduciary malpractice claim."¹⁷¹ However, in doing so, the Court may have opened the door to additional litigation at the state level.¹⁷² State supreme courts in both New York and Pennsylvania have since affirmed the right of patients to sue their health insurers for negligence, and New Jersey (among other states) has legislated patients' rights to sue employer-paid health plans.¹⁷³

Before the era of managed care, the Washington State Supreme Court endeavored to foster a radical shift in the medical standard of care Helling v. Carey,¹⁷⁴ a malpractice paradigm. action In against ophthalmologists, medical expert testimony tried to establish no requirement for routine glaucoma testing for patients less than forty years old.¹⁷⁵ However, the court moved to step outside the traditional legal construct for medical malpractice. Quoting Justice Learned Hand, the court emphasized that "[c]ourts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."¹⁷⁶ Disregarding the expert testimony, the court made its own value judgement: "We therefore hold, as a matter of law, that the reasonable standard that should have been followed under the undisputed facts of this case was the timely giving of [a] simple, harmless pressure test to the plaintiff and that, in failing to do so, the defendants were negligent."¹⁷⁷ The court thus demanded a higher standard than the professional standard, in effect adjudicating strict liability.¹⁷⁸ Although Helling is not followed today, it demonstrates the courts' potential to explore nontraditional legal remedies to the standard of care issue.

Consumer dissatisfaction with the present health care system is a popular topic. TIME magazine notes:

If you visited a doctor any time recently, you know the routine. You wait an hour for a 10 minute once-over, and you can't get an aspirin tablet or a band-aid—let alone a referral—without six bean counters and a dozen paper pushers eyeballing your entire medical history.¹⁷⁹
Clearly, the health care industry strives to control costs.¹⁸⁰ Managed care entities utilize protocols and guidelines for care, creating average lengths of stay for hospitalizations due to particular conditions, in addition to "cookbook" approaches to both outpatient and inpatient diagnostic and treatment decisions.¹⁸¹ The medical standard of care now competes with financial pressures that threaten to usurp it. Not only must physicians today attend educational seminars to learn of new advances in their field, they now attend classes to learn how to code their procedures to satisfy managed care business pressures.¹⁸² Thus, while physicians of past eras have molded the standard of care unfettered by such concerns, today's physicians are themselves being molded by corporate/business interests.¹⁸³

The issue remains whether these business/financial interests can effectively and ethically co-exist with an appropriate standard of care. Avedis Donabedian helped develop quality control systems for hospitals and has been described as "the father of quality assurance."¹⁸⁴ He believes that "healthcare is a sacred mission...a moral enterprise and a scientific enterprise but not fundamentally a commercial one."¹⁸⁵

III. RECENT LITERATURE ON THE MEDICAL STANDARD OF CARE IN JUXTAPOSITION WITH MANAGED CARE REALITIES

Legal scholars have written hundreds of articles attempting to define and analyze the complex medico-legal interplay between managing medical care and maintaining the quality of that care.¹⁸⁶ Various authors propose to hold managed care entities accountable for their actions in either tort or contract theory.

Wertheimer, for example, argues in favor of the doctrine of respondent superior.¹⁸⁷ She holds HMOs responsible as *de facto* employers of physicians, but points out that HMOs often persuade courts that physicians ultimately make independent decisions.¹⁸⁸ Her solution is to hold HMOs to a reasonableness standard, since "overruling the reasonable exercise of medical judgment is itself negligence."¹⁸⁹ Thus, if a HMO reasonably denies authorization for care (e.g., when claiming the proposed care is unnecessary), the HMO is protected from liability under a reasonableness doctrine, but if denial is unreasonable, HMOs would be held accountable.

Advocacy for a "reasonableness standard" suggests HMOs have a duty to avoid interfering with the provision of adequate health care to patients. Juries may rule on breach of that duty based upon their own common knowledge and reasoning. But if a "professional" standard of care still exists, how could such a case be effectively tried in court? Surely a HMO would point the finger of responsibility at the ultimate authority—the treating physician.¹⁹⁰ How could the "professional" standard of a physician be separated from a "reasonable" standard of a HMO, especially when the HMO utilizes protocols developed by medical physician experts with their own professional standards?¹⁹¹ Wertheimer argues that physicians' decisions are controlled by HMOs and corporate interests to a point where HMOs are setting standards and making it difficult, if not impossible, for doctors to deviate from them.¹⁹²

Danzon discussed the potential "mine field" of managed care liability under tort law, but ultimately rejected the concept:

Health plans should be liable in tort for negligence only in cases of negligent credentialing. Liability for negligent performance should be placed solely on the individual provider, who is usually best placed to make and monitor precautions in the delivery of medical care. Adding liability of plans, under theories of vicarious, agency, or enterprise liability, serves only to add an additional deep pocket defendant. To the extent that this increases the frequency of erroneous findings of liability, the ability of managed care to control insurance-induced overuse and improve efficiency in health care delivery will be obstructed.¹⁹³

While Wertheimer holds HMOs completely responsible for care, Danzon claims it is the providers who bear sole responsibility for decisions.¹⁹⁴ However, Danzon goes on to advocate contract-based claims against managed care entities, in the context of "contract shifting of liability between provider and plans," as a means of fostering gains in health care economic efficiency.¹⁹⁵ Despite this, she criticizes the *Fox* decision, particularly the punitive damages award, arguing that punitive damages should not be permitted under such a contract theory, and that evidence on incentive based HMO contracts should not be admissible evidence in coverage denial cases.¹⁹⁶ She believes that punitive liability under such circumstances would risk obstructing efficiency in the managed care industry.¹⁹⁷

Hirshfeld seems to advocate a new form of HMO-patient contract:

[H]ealth plans should be required to disclose information to patients about their own outcomes and the techniques that they use to eliminate unnecessary care. This information should be drafted in easily understood language so that patients can decide whether they are comfortable with the combination of price and risk used by the health plan.¹⁹⁸

Yet Hirshfeld claims that patient remedies would still be grounded in tort theory, not contract theory. He advocates enhanced managed care liability through modification of "the tort of bad faith insurance settlements."¹⁹⁹ In terms of enterprise liability, he is in agreement with Danzon, noting that such liability could be counterproductive if managed care organizations felt compelled by liability concerns to exert even more control over physicians.²⁰⁰

Hirshfeld's vision of patient "consent" to managed care restrictions appears to bolster the contract theory construct to managed care liability.²⁰¹ In an earlier article on standard of care issues, Hirshfeld had proposed keeping "patient-oriented" standards as a foundation for practice guidelines in which physicians would be legislatively protected from tort liability.²⁰² But who would draft such guidelines, and how would providers, managed care organizations, and legislators establish a methodology for agreement on scope and/or acceptable deviations from such guidelines?²⁰³

A recent survey of physicians found medical decision-making under managed care to be restricted by "range," by "degree," and by "latitude," suggesting a subtle form of control.²⁰⁴ Arguably, non-overt managed care influences may not be amenable to either legislation or professional guidelines. To illustrate the potential subtlety of the problem, the reader is invited to consider the following hypothetical example:²⁰⁵

Mr. Smith is a sixty-six year-old widower with a history of congestive heart failure and osteoarthritis. He is insured through a Medicare-approved HMO. For several months, he has had difficulty walking due to severe right hip pain. He is informed by his doctor that he needs a hip replacement due to the severity of his arthritis. He agrees to the surgery, and his physician obtains appropriate pre-authorization from the HMO without difficulty. The surgery is performed successfully, and Mr. Smith begins receiving physical therapy in the hospital the next day. However, he feels very fatigued and is easily winded by attempts to walk (even when using a walker). X-rays of his lungs show mild exacerbation of his congestive heart failure, so his cardiac medications are adjusted. Although Mr. Smith no longer feels short of breath, he still tires easily. His physician advises the hospital's nurse case manager of the patient's decompensated status.

Let's say Mr. Smith's HMO had originally pre-approved a three to four day hospital stay. How had they arrived at that decision? Managed care organizations today contract with data-analysis and accounting firms, seeking statistical justification for clinical pathway decisions, which reduce the costs of diagnosis and treatments.²⁰⁶ These firms, and their analyses, are not necessarily subject to strict scientific scrutiny in an academic setting.²⁰⁷ Although no one at the HMO had examined Mr. Smith, he may be viewed as a statistically average patient undergoing an elective hip replacement.²⁰⁸ The hospital's nurse case manager now calls the HMO's case manager. After playing phone tag for some hours, the conversation may ultimately go something like this:

HOSP:	Hi Denise. This is Mary from Valley Hospital. I'm calling about Mr. Smith
HMO:	Yes, I have his information on the screen here. He should be ready for discharge tomorrow, right?
HOSP:	Well, we're concerned about his cardiac status. He was in heart failure a couple days ago.
HMO:	Yes, I remember getting that message on my voice mail. But how is it now?
HOSP:	The chest x-ray today was clear, but the patient is still easily fatigued when he uses the walker in physical therapy. The doctor doesn't want to discharge him yet.
HMO:	He should get stronger when he's transferred to the Rehab center.
HOSP: HMO:	I don't know. His daughter was here and she's also concerned. O.K., here's what we'll do. I'll allow him one extra day in the hospital. Then, if there is no congestion on a repeat chest x-ray, he has to go to rehab
HOSP:	His daughter wants him to go to the rehabilitation hospital here in Lakeville.
HMO:	We don't have a contract with them for these elective cases. He can go to a subacute center.
HOSP:	You mean one of the local nursing homes with a rehabilitation wing?
HMO:	Yes. Either Cedar Knolls or Belleville.
HOSP:	What about Victoria Park? That nursing home has a full time rehabilitation specialist.
HMO:	Sorry, we don't have a contract with that nursing home. Besides, all he needs is some therapy, and the other places can give him that.

HOSP: O.K., Can I have the pre-authorization number?

The hospital nurse case manager now calls the patient's attending physician, Dr. Daye.

HOSP:	Dr. Daye?	This is M	lary from	Valley Ho	ospital ca	ase management.
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- **DOC**: Hi, how are you?
- **HOSP:** Fine. I'm calling you about Mr. Smith. I got pre-authorization from his HMO to get him over to subacute rehab.
- DOC: I thought the family wanted the rehabilitation hospital down the

street. He would do well there. I send all of our regular Medicare cases there.

- **HOSP:** We can't do it. His HMO only allows subacute rehab at the nursing homes for elective hip surgery.
- **DOC**: O.K., send him to Dr. Clark at Victoria Park.
- HOSP: No, the HMO doesn't contract with them.
- **DOC:** Where then?
- HOSP: Cedar Knolls or Belleville.
- **DOC:** But those are just regular nursing homes.
- **HOSP:** I don't know what to tell you doctor. The family has already agreed. We're just waiting for your discharge order.
- DOC: We're still keeping him for the congestive heart failure, though.
- HOSP: The HMO is only giving him one more day. They want him out.
- DOC · Who did you speak to?
- HOSP: The case manager.
- **DOC:** Is the case manager a doctor?
- HOSP: No, but I think she might be a nurse.
- **DOC**: I'll only discharge him with a clear chest x-ray. (hangs up)

Dr. Daye feels frustrated. He had originally wanted to keep Mr. Smith hospitalized two or three more days for observation. However, the Utilization Management coordinator employed by his hospital (a physician named Dr. Duff), has been accusing him of unnecessarily delaying discharges and costing the hospital money. He recently received the following memorandum from Dr. Duff (as did all of the medical staff, not only at this hospital, but at all ten hospitals in the hospital corporation's statewide chain):

We are all affected by Utilization Management decisions—physicians and hospitals alike. We as physicians are busy treating patients and none of us like our decisions being questioned by others, including the UM Committee. However, all of us wish to provide quality care to our patients.

What is the definition of quality? Traditionally it has been defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcome and are consistent with current professional knowledge. In recent years questions of cost and limited resources have entered the equation. You and I know we have to strike a balance so that everyone is happy—patients, other providers, and payers.

Since Utilization Management focuses on providing appropriate care in the appropriate setting at the appropriate time, the UM Committee is really a quality committee. Its main role is to study, monitor, and report on issues impacting quality in the process of health care delivery; and to educate our physicians to practice in a way that permits good medical decisions, yet minimizes denials and challenges from insurance carriers.

When we concentrate on the outcome, it increases the efficiency of the health care delivery process and quality and patient satisfaction increase while costs decrease. As a result, the market share of our facility will go up.

The idea is simple, but execution is difficult. However, it is doable with collaborative teamwork. We need your support.²⁰⁹

Mr. Smith's chest x-ray is repeated the next day. The radiologist reports: "Clear except for possible mild pulmonary vascular congestion. Follow-up studies if clinically warranted." Dr. Daye sees Mr. Smith on hospital rounds that morning. On examination, his lungs sound clear, but the patient still feels fatigued.

- **DOC:** You started the physical therapy already right?
- SMITH: Yeah, but I haven't done much since I've been so tired.
- **DOC:** Well, it says here in the chart that you've been walking up to ten feet with the walker. And the orthopedist says the surgical site is healing well.
- SMITH: Yes. He said I can go for rehab as soon as you clear me for discharge.
- **DOC:** O.K., I'll discharge you to rehab today. But make certain you let the staff there know if you have any breathing problems.
- SMITH: All right, doc. The HMO covers the rehab, right?
- **DOC:** Yes, so long as you go to either Cedar Knolls or Belleville.
- **SMITH:** I think my daughter already discussed that with the nurse case manager. She already chose Cedar Knolls. Thanks, doc.

Mr. Smith is transported by ambulance to the nursing home, where he receives additional physical therapy. He made progress over the following two weeks, but not as much as his physical therapist had expected. He continued to have problems not only with generalized fatigue, but he also occasionally became short of breath. Nursing staff informed the facility's internist, who saw Mr. Smith twice over the two weeks, ordered another chest x-ray, and adjusted his medications. The chest x-ray still appeared clear. His surgical site was closed and almost completely healed (except for the residual surgical scar). The leg still had some post-operative swelling, and Mr. Smith still complained about hip pain, along with shortness of breath while walking. He could now walk up to one hundred feet with a walker, with no one assisting him.

The HMO case manager then calls the nursing home case manager.

HMO:	How's Mr. Smith doing?
NH:	Fine, but the therapist feels he could do even better. He still has
	some pain at the hip.
HMO:	How far can he walk?
NH:	One hundred feet.
HMO:	Without assistance?
NH:	Without assistance, but he still needs a walker, and he gets winded very easily.
HMO:	Well, he really needs to be discharged home. Walking one hundred feet without assistance meets our criteria for discharge.
NH:	But I spoke to the doctor yesterday, and he was thinking of keeping him another week.
HMO:	We will not pay for any additional time at your facility. He can

HMO: We will not pay for any additional time at your facility. He can get outpatient physical therapy, and his family will have to arrange for home health if they feel he needs it. He meets our criteria for discharge. (The conversation is concluded.)

The nursing home case manager now discusses the situation with the nursing home's chief administrator. The administrator explains to the case manager how important the HMO contract is to the nursing home's financial survival, thus necessitating compliance with HMO guidelines. He expresses concern that the doctor is not looking at the situation from the HMO's point of view (nor the nursing home's point of view), and considers the possibility of contracting alternative doctors to follow patients at the nursing home in the future. He advises his case manager to make appropriate home arrangements for the patient. The case manager then calls the doctor.

- NH: We need to send Mr. Smith home. His HMO is cutting him off. I've made arrangements for visiting nurse service, meals-onwheels, and outpatient physical therapy. I also ordered a walker for him to take home.
- **DOC:** I'll call the nursing station. If his vitals are still normal, we will send him home. His family is O.K. about him going home?
- NH: Oh yes! They don't want to have to pay anything out-of-pocket, so they want him home as soon as his HMO time is ended.
- **DOC:** It's too bad, you know. If he had traditional fee-for-service Medicare, he could stay longer.²¹⁰ Does he realize that? You know, if you want, I could send a formal protest to the HMO, and try to go through their appeals process.
- NH: I don't think the patient realizes the difference between Medicare and HMO Medicare. Listen, doctor, I really appreciate your cooperation on this. I know we could formally

appeal the HMO's decision, but we don't want to risk losing their business in the future.

DOC: I understand. Look I really think he can go home now. We have had other patients in his situation who we sent home with no problems. With the HMOs, this is the new standard of care. (sighs)

Mr. Smith is discharged home after two weeks at the nursing facility. The following week, he is admitted to the hospital's intensive care unit. Apparently he was having multiple pulmonary emboli (not picked up on routine chest x-rays), along with an infection involving the hip replacement apparatus. In retrospect, his shortness of breath and hip pain should have been investigated more carefully, and may have been noticed and effectively treated had he remained in an inpatient setting.²¹¹

Why did his physicians feel comfortable agreeing with treatment and/or discharge decisions instigated by an insurance carrier? Because the mentality of cost-containment has blurred the definition of quality care/standard of care. Some legal scholars believe the answer to this problem lies in the establishment of a socially and legally recognized forum for "physician advocacy."²¹²

CONCLUSION

Proposed solutions to this standard of care dilemma vary across the spectrum of legal theories and socio-political views. Some legal scholars claim society ultimately demands compliance with the traditional medical professional standard of care,²¹³ while others propose that hospitals, HMOs, and physicians be allowed variable standards of care based upon society's desire to control costs.²¹⁴ Such variable standards could purportedly be applied under tort theory,²¹⁵ or under contract theory.²¹⁶ Regardless of how these variable standard proposals have been constructed, they appear to saddle courts with burdensome cost-versus-benefit inquiries and/or contract analyses of variations at the level of the individual health plans. Proponents of variable standards appear to assume consumer knowledge and acquiescence to a reduced standard of care, which they purportedly "bargained" for.²¹⁷ Does this ring true for the factory worker who obtains HMO coverage for herself and children through her employer? Does Mrs. Iones know that hospital A has a managed care contract that pressures physicians and the hospital to discharge cardiac patients earlier than hospital B?²¹⁸ And intrinsic to this entire issue of "standard of care," is it not contradictory to say the issue is being forced upon the public by the constraints of rising health care costs, while HMO and other corporate

health care interests reap profits through the *de facto* rationing of care to patients?²¹⁹ To some, the beguiling nature of this issue poses a question akin to one of good versus evil: "No one can serve two masters, for either he will hate the one and love the other, or he will be devoted to the one and despise the other. You cannot serve G-d and mammon."²²⁰

Even assuming managed care interests may one day be held accountable for their actions, the question remains: How shall the standard of care be defined? This Article has traced the development of the medical standard of care through 500 years of English and American law. Through a culture of deference to superior medical knowledge, combined with historical happenstance (e.g., the Black Plague and King Henry VIII's desire for a royal-chartered College of Physicians and Surgeons), physicians were placed on society's pedestal, entrusted with setting their own standards of care. Thus, the legal community and courts recognized a medical professional standard, which shielded physicians from much of the liability commonly applicable to business commercial interests. However, recent cost-cutting trends may degrade and corrupt the historical trust granted to physicians. In order to comport with the reality of modern day health care, American jurisprudential constructs on medical standard care must evolve in conjunction with these modern trends. Given the competing views of tort theory versus contract theory, traditional standards versus variable standards, and patient advocacy versus cost-containment, it appears the direction of this evolution remains to be defined.

References

1. WILLIAM PROSSER, LAW OF TORTS § 32 (4th ed. 1971).

2. Id.

3. See William M. Sage, *Physicians as* Advocates, 35 HOUS. L. REV. 1529, 1536 (1999) (defining "managed care" as follows: "[A]s a general matter, managed care reduces costs in limiting access to health care professionals and prescreening proposed treatments for appropriateness.").

4. PROSSER, supra note 1.

- 5. Id.
- 6. Id.
- 7. Id.
- 8. Id.
- 9. Id.
- 10. Id.

11. See id. (noting the courts have had "a healthy respect...for the learning of a fellow profession, and...reluctance to overburden it with liability based on uneducated judgement").

12. See id. (noting that "[this] result is closely tied in with the layman's ignorance of medical matters and the necessity of expert testimony").

13. 709 P.2d 517 (Ariz. 1985) (en banc).

14. Id. at 522 (citing PROSSER, LAW OF TORTS, throughout its discussion about a reasonable man standard versus a professional standard of care).

15. Id.

16. Id. at 517.

17. L.B. CURZON, ENGLISH LEGAL HISTORY 253-54 (1968).

18. Id. at 254.

19. WILLIAM LLOYD PROSSER, SELECTED TOPICS ON THE LAW OF TORTS 380-81 (1953) [hereinafter Selected Topics]. 20. See generally J.H. BAKER & S.F.C. MILSOM, SOURCES OF ENGLISH LEGAL HISTORY: PRIVATE LAW TO 1750, at 340-97 (1986).

21. SELECTED TOPICS, supra note 19.

22. LI MS. Hale 137 (1), fo. 150 (eyre of Nottingham) (1329), *reprinted in* BAKER & MILSOM, *supra* note 20, at 340-41.

23. Id.

24. Id.

25. Id; see also WEBSTER'S INTERNATIONAL DICTIONARY 824 (3d ed. 1976) (defining the British term "farrier" as either a veterinarian, "especially when practicing without full qualification," or a blacksmith who shoes horses).

26. The Oculist's Case, cited in Hale, supra note 22.

27. See BLACK'S LAW DICTIONARY 120 (7th ed. 1999) (defining "assumpsit" as "[a]n express or implied promise, not under seal, by which one person undertakes to do some act or pay something to another").

28. SELECTED TOPICS, *supra* note 19; *see* also BLACK'S LAW DICTIONARY, *supra* note 27, at 1509 (explaining "trespass on the case" as follows: "at common law, an action to recover damages that are not the immediate results of a wrongful act, but rather a later consequence. This action was the precursor to a variety of modern-day tort claims....").

29. SELECTED TOPICS, *supra* note 19, at 382.

30. HLS MS. 169, unfol. (C.P.) (1443), reprinted in BAKER & MILSOM, supra note 20, at 395. Although the parties ultimately settled their case (involving the mishandled transport of wine), one justice made the following medical analogy: "If my arm is broken, and I make a covenant with someone to put [a cast on] it, and he does not do so, whereby my arm is lost, I shall have an action of trespass on my case." *Id.* at 396.

31. See id.

32. See W.S. HOLDSWORTH, A HISTORY OF ENGLISH LAW 385-86 (1923).

33. Id. (stating that "medieval society was regarded as divided into very distinct orders of men...bound by the particular rules which applied to that particular order...considered to be bound by their calling to show a certain degree of skill..."). As noted previously, physicians prior to the fifteenth century were often compared to farriers by ruling justices who refused to profession hold either liable for negligence. See also ROBERT C. PALMER, ENGLISH LAW IN THE AGE OF THE BLACK DEATH, 1348-1381, at 190-94 (1993).

34. PALMER, supra note 33, at 186.

35. Id. at 185-87.

36. Id.

37. Id. at 187.

38. See id. at 188-89 (noting also a brief period after the Black Plague, when physicians accused of malpractice were liable for "criminal mayhem," rather than a civil suit. The chancery ended this shortlived jurisprudential detour by handling such suits as civil matters).

39. Id. at 195.

40. See HOLDSWORTH, supra note 32, at 386.

41. See SELECTED TOPICS, supra note 19, at 387.

42. Y.B. Hil. 48 Edw. III, fo. 6, pl. 11 (1374), *reprinted in* BAKER & MILSOM, *supra* note 20, at 360.

43. Id.

44. See id.

45. Y.B. Tas. 11 Ric. II, p. 223, pl. 12 (1388), *reprinted in* BAKER & MILSOM, *supra* note 20, at 362 (involving a physician's alleged failure to cure a case of ringworm).

48. Id.

49. SELECTED TOPICS, *supra* note 19, at 388.

50. J.H. BAKER, AN INTRODUCTION TO ENGLISH LEGAL HISTORY 346-50 (2d ed. 1979).

52. See id. at 346.

53. Id.

54. See id. at 347-48.

55. Id. at 346.

56. See BAKER & MILSOM, supra note 20, at 362.

57. See generally PALMER, supra note 33, at 190-94.

58. See id.

59. See BAKER, supra note 50, at 346.

60. See Royal College of Physicians, at http://www.rcplondon.ac.uk/college/abo ut_history.htm. (last visited Sept. 29, 2000) (explaining the history and mission of the Royal College of Physicians and Surgeons).

62. Id.

63. Id.

64. See 16 CHARLES VINER, A GENERAL ABRIDGMENT OF LAW AND EQUITY 338-45 (2d ed. London, Robinson, Payne & Brooke 1793) (containing reprint of the Royal College original charter, along with legal commentary).

- 65. Id. at 339.
- 66. Id. at 339-41.
- 67. Id. at 341.
- 68. Id. at 344.
- 69. Id. at 343.

70. Id. at 344 (indicating the College of Physicians was "impowered to inspect, govern, and censure [physicians]...[The College of Physicians] are Judges of Record...").

71. Id. at 345.

^{47.} Id.

^{51.} See id.

^{61.} Id.

72. 8 A. WOOD RENTON, LAWS OF ENGLAND 322-51 (1920). Although plaintiffs could allege "gross evidence of want of skill," expert defense witnesses easily refuted such charges. Further, some courts still viewed malpractice as a breach of contract, hence difficult to prove without a written instrument. *See id.*

73. 2 Wils. 359, 95 Eng. Rep. 860 (K.B. 1767), noted in Allan H. McCoid, The Care Required of Medical Practitioners, 12 VAND. L. REV. 549, 550 (1959).

74. 8 East 348, 103 Eng. Rep. 376 (K.B. 1807), noted in McCoid, supra note 73, at 550.

75. Id.

76. 11 Price, 400 (1822), discussed in Francis H. Bohlen, Studies in the Law of Torts 92 (1926).

77. Id.

78. BOHLEN, supra note 76.

79. 5. B (N.C.) 733 (1839), quoted in BOHLEN, supra note 76.

80. Id. at 93.

81. See Jay A. Gold, Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship, 333 NEW ENG. J. MED. 466 (1995) (describing English law maxim as "Doctor knows best").

82. 8 C&P 475 (1838), noted in 33 THE DIGEST: ANNOTATED BRITISH, COMMONWEALTH AND EUROPEAN CASES, 264 (1982) [hereinafter THE DIGEST] (a treatise summarizing nineteenth century British case holdings, the specific facts of which are not discussed).

83. Id.

84. 3 F&F 35 (1862), noted in THE DIGEST, supra note 82, at 264-65.

85. Id.

86. See PROSSER, supra note 1.

87. See 8 MEWS' DIGEST OF ENGLISH CASE LAW 788 (2d ed. 1925) [hereinafter MEWS' DIGEST] (reporting decisions of English, Scottish, and Irish courts dating back to the nineteenth century).

88. Id.

89. Id. at 772.

90. *Id*; *see also* 3 LAW REPORTS, DIGEST OF CASES 3598 (Arthur Paul Stone ed., London, William Clowes & Sons 1892).

91. MEWS' DIGEST, *supra* note 87, at 790.

92. JOSIAH W. SMITH, A MANUAL OF COMMON LAW 1 (Edward Chase Ingersoll ed., Washington City, W.H. & O.H. Morrison, 1875) (quoting from an inscription on the cover page).

93. *Id.* at 442. The author of this treatise was an attorney serving as commissioner in charge of revising the local laws at Washington, D.C., thus furthering the notion of English common law influencing American law well into the nineteenth century. *Id.* at cover page.

94. John G. Fleming, *Developments in the* English Law of Medical Liability, 12 VAND. L. REV. 633, 634-35 (1959). Professor Fleming attributed the trend in part to the advent of an impersonal national health care bureaucracy, born of the British National Service in the late 1940s, as well as increased access to lawyers through utilization of government-funded legal aid programs.

95. 2 Root 90 (Conn. 1794), discussed in McCoid, supra note 73, at 550.

98. 22 Pa. (10 Harris) 261, 267-68 (1853), quoted in McCoid, supra note 73, at 550 n.10.

99. Id. at 550.

100. 27 N.H. 460, 469-72 (1853), quoted in McCoid supra note 73, at 551 n.11.

101. Id.

102. Id.

103. See McCoid, supra note 73, at 550.

^{96.} Id.

^{97.} Id.

104. Patricia M. Danzon, Tort Liability: A Minefield for Managed Care?, 26 J. LEGAL STUD. 491, 518 (1997) (discussed infra).

105. McCoid, *supra* note 73, at 559. The "similar localities" rule has since been modified in most jurisdictions. *E.g.* Vergara v. Doan, 593 N.E.2d 185, 188 (Ind. 1992) (Givan, J., concurring) (explaining that physicians must now practice with the same skill and care of similar practitioners "acting in the same or similar circumstances").

106. Clarence Morris, Custom and Negligence, 32 COLUM. L. REV. 1147, 1163-64 (1942) (a comprehensive source of historical information on standard of care and negligence theory).

107. Id. at 1164.

108. Id.

109. Id.

110. Id.

111. McCoid, *supra* note 73, at 560; *see also* Aiello v. Muhlenberg Reg'l Med. Ctr., 733 A.2d 433, 441 (N.J. 1999) (noting that professional conduct must be evaluated by the applicable standard of care required of a physician in the same field).

112. McCoid, *supra* note 73, at 559 (seemingly lowering the standard of care required).

113. 8 N.E. 832 (III. 1886), discussed in McCoid, supra note 73, at 559.

114. Id.

115. See FED. R. EVID. 104, 105 (regarding jury hearings and instructions on admissibility; FED. R. EVID. 702, 703 (regarding judicial discretion for allowing expert testimony); see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592-93 (1993) (holding judge may act as gatekeeper for inclusion versus exclusion of expert testimony).

116. 32 F.2d 394 (D.C. Cir. 1929).

117. Id. at 395-96.

118. Id. at 396 (stating there was no evidence that the physician "failed to exercise his best judgment [nor that] he failed to exercise the care and skill ordinarily possessed and exercised by others in the profession").

119. Meyer v. McNutt Hosp., 173 Cal. 156, 158-59 (1916).

120. Brown v. Shortlidge, 98 Cal. App. 352, 355 (1929).

121. Gannon v. Elliot, 19 Cal. App. 4th 1, 6 (1993) (involving a plastic instrument left perioperatively in a hip joint during hip surgery).

122. See id. at 7; see also Dahlquist, Common Knowledge in Medical Malpractice Litigation: A Diagnosis and Prescription, 14 PACIFIC L.J. 133, 136-42 (elaborating on the common knowledge doctrine).

123. Matson v. Naifeh, 595 P.2d 38, 40 (Ariz. 1979) (alleging medical malpractice when treatment for iatrogenic hematoma was delayed, resulting in permanent nerve damage).

124. E.g., Stearrett v. Newcomb, C.A. No. 83C-SE-74, 1988 Del. Super. LEXIS 248, at *6 (Del. Super. Ct., July 20, 1988) (noting that "Delaware does not recognize the 'common knowledge' doctrine").

125. 473 N.E.2d 1131 (Mass. 1985).

126. Id. at 1135.

127. See id. at 1136.

128. Id. at 1135.

129. 551 P.2d 334 (Cal. 1976), discussed in Stepakoff, 473 N.E.2d at 1135.

130. Id.

131. 706 A.2d 721 (N.J. 1998) (involving alleged negligent prescription of Cipro to a pregnant patient).

132. *Id.* at 734. The court notes, however, that a physician is not "immune from liability [simply if] he or she does his or her best."

133. 709 A.2d 238 (N.J. Super. Ct. App.

Div. 1998), aff'd, 733 A.2d 456 (N.J. 1999).

134. Id. at 251; see also id. at 249 (criticizing arguments that favor physician paternalism, describing such paternalism as "anachronistic").

135. 239 Cal. Rptr. 810 (Cal. Ct. App. 1986).

136. Id. at 812.

- 137. Id.
- 138. Id. at 813.
- 139. Id.
- 140. Id. at 814.
- 141. Id.
- 142. Id.
- 143. Id.
- 144. Id. at 816.
- 145. Id. at 817.
- 146. Id.
- 147. Id. at 810.

148. See id. at 818-19 (suggesting the decision to discharge the patient home was within the appropriate medical standard of care).

- 149. Id.
- 150. Id. at 819-20.
- 151. Id.
- 152. Id.
- 153. Id. at 819.

154. 271 Cal. Rptr. 876 (Cal. Ct. App. 1990).

155. Id. at 885 (noting that "[t]here remain triable issues of material fact as to [a utilization review company's] liability for tortious interference with the contract of insurance between the decedent and the [insurance company]...").

156. Id. at 878.

- 158. Id. at 884.
- 159. Id. at 885.

160. See id. Compare with Stepakoff v. Kantor, 473 N.E.2d 1131, 1135 (Mass. 1985). Stepakoff involved a proposal to divide the standard of care for two aspects of medical decision-making and conduct, whereas *Wilson* involved bifurcation between physician conduct and HMO conduct.

161. Danzon, *supra* note 104, at 505 (discussing an unpublished case originally noted in David P. Maslen, *Employer Managed Care Liability: Defining and Managing the Risk*, J. COMPENSATION BENEFITS, July-Aug. 1995, at 5.

- 162. Id.
- 163. See id.
- 164. Id. at 517.

165. ERISA is the Employee Retirement Income Security Act of 1974, § 3 (1) (A), 29 U.S.C. § 1002 (1) (A) (1974); see also Janet Spicer, Professional Liability Insurance: The Clinical Environment, N.J. MED., Aug. 2001, at 41, 42 (explaining that ERISA was promulgated by the late Senator Jacob Javits to encourage large multi-state companies to provide health coverage to their employees. To accomplish this, companies wanted immunity from widely differing regulatory state health care laws. ERISA became law in 1974, exempting all employer-sponsored health plans, including HMOs, from these state laws, even in medical malpractice cases where the plans' decisions resulted in permanent injury, or even death. Employer-sponsored health organizations thus use ERISA to shield themselves from liability, a tactic that has always engendered controversy.).

166. Danzon, supra note 104, at 517.

167. Id.

168. Durham v. Health Net, No. C-94-3575, 1995 WL 429252 (N.D. Cal. 1995), *aff*'d, 108 F.3d 337 (9th Cir. 1997).

169. See id. at *3 (holding that a restaurant employee cannot sue an HMO under ERISA for damages after the HMO withheld a bone marrow transplant for breast cancer).

^{157.} Id. at 880.

170. Pegram v. Herdrich, 530 U.S. 211, 237 (2000).

171. Id.

172. M. Gregg Bloche & Peter D. Jacobson, The Supreme Court and Bedside Rationing, 284 JAMA 2776, 2777 (2000) (referring to Pegram v. Herdrich, noting "the Court thereby created an opening for myriad state law challenges to health plans' utilization management methods," and "mixed treatment and eligibility decisions beyond the reach of ERISA's are preemptive shield and therefore subject to state lawsuits."); see also Thomas R. McLean & Edward P. Richards, Managed Care Liability for Breach of Fiduciary Duty After Pegram v. Herdrich: The End of ERISA Preemption for State Law Liability for Medical Care Decision Making, 53 FLA. L. REV. 1 (2001) (agreeing that Pegram facilitates the theory of managed care liability for malpractice).

173. Spicer, supra note 165, at 43. But see Editorial, Curing the Patients' Bill of Rights, N.Y. TIMES, Sept. 4, 2001, at A22 (indicating recent state patients' rights legislation has yet to yield any successful lawsuits against HMOs).

174. 519 P.2d 981 (Wash. 1974).

175. Id. at 983.

176. Id.

177. *Id.* at 984 (holding an ophthalmologist to a professional negligence standard that appeared to be akin to strict liability in a malpractice action for failure to diagnosis glaucoma).

178. See BLACK'S LAW DICTIONARY, supra note 27, at 926 (defining strict liability as "[1]iability that does not depend on actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe").

179. Steve Lopez, The Single-Doctor HMO: A Small Town Dumps its Provider for a Rebel *Medic*, TIME, Feb. 26, 2001, at 8 (reporting a physician who dropped out of all HMOs as stating: "I'm tired of doing the wrong things as a doctor. I want to do the right things for a while...").

180. James C. Robinson, *The End of Managed Care*, 285 JAMA 2622, 2622 (2001) (stating that "[m]anaged care embodies an effort by employees, the insurance industry, and some elements of the medical profession to establish priorities and decide who gets what from the health care system.... The strategy of giving with one hand while taking away with the other, of offering comprehensive benefits while restricting access through utilization review, has infuriated everyone involved.").

181. See id.

182. Emergency Conference on the Final Stark II Regulations, Apr. 2001 (pamphlet publicizing such a coding conference for physicians); see also Mary LeGrand, Using CPT Frequency Reports to Analyze E&M Use, N.J. MED., Feb. 2001, at 35 (noting that "understanding utilization patterns can assist the physician in determining whether significant differences exist between the physician's billed services and group or national norms").

Consumer 183. See, e.g., Direct to Advertisements for Glucophage XR, MED. LETTER, Mar. 19, 2001, at 25. Business interests are not confined to managed care organizations and large hospital chains: Pharmaceutical companies are an additional source of influence over medical standard of care. A nonprofit medical publication recently discussed a new diabetes drug being advertised directly to patients (as well as to doctors). The "new" drug is a modified version of an old drug. At least one scientific study showed the new drug to have more adverse side effects than the old drug. Why then is the new drug

being aggressively marketed over the chemically similar old drug? The medical publication points out that the older drug is now off patent and will soon be available as a much cheaper generic drug. Thus, the "new" drug will remain on patent and will remain a potential source of profit for pharmaceutical companies.

184. Enter-stumbling?, N.J. MED., Feb. 2001, at 1, 2.

185. Id.

186. Such writings are not confined to legal publications. See, e.g., Gregory Webster, Serving Two Masters: Medical Practice vs. Administrative Ethics, 282 JAMA 1678. 1678-79 (1999)(arguing that "[s]ociety should expect physicians, as professionals, able to be to make responsible decisions about the allocation of medical resources"); see also Leslie Ray, Linking Professional and Economic Values in Health Care Organizations, 10 J. CLINICAL ETHICS 216-23 (1999) (proposing an "ethical" approach for addressing the tension between controlling the cost of care and maintaining quality of service).

187. Ellen Wertheimer, Ockham's Scalpel: A Return to a Reasonableness Standard, 43 VILL. L. REV. 321, 323 (1998). She argues that physicians in fact do not make independent decisions under managed care, because managed care length-of-stay decisions are integral to patient care, influence physician judgment, and violate the purported prohibition against the corporate practice of medicine. Id. at 325-31.

188. Id.

189. Id. at 358.

190. As noted in *Wickline*, discussed supra.

191. Spicer, *supra* note 165, at 43 (stating that "doctors in most states still bear the majority of the burden. When a

plan obstructs proper treatment, physicians can even be punished for not fighting back against the HMO. Therefore, doctors who do not appeal bad decisions put themselves in a vulnerable position."); see also Megan L. Sheetz, Note, Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability for Developers and Insurers of Clinical Pathways, 63 BROOK. L. REV. 1341, 1345 n.4 (1997) (noting that HMO fears of increased liability from practice utilization standards can be minimized by using the word "guidelines" instead of "standards," to specify "permissive" rather than "mandatory" directives for providers, thus keeping ultimate liability in the sphere of the providers). Managed care organizations are also advised to make their guidelines "vague," to help them prove "that a physician made poor decisions." Id. at 1345 n.4.

192. See Wertheimer, supra note 187.

193. Danzon, supra note 104, at 518-19.

194. Id.

195. Id. at 519.

196. See id. at 510-11.

197. Id; see also Sheetz, supra note 191, at 1345 n.4.

198. Edward B. Hirshfeld & Gail H. Thomason, *Medical Necessity Determinations: The Need for a New Legal Structure*, 6 HEALTH MATRIX 3, 50 (1996). Hirshfeld is the Director of the Health Law Division of the Office of General Counsel of the American Medical Association. *Id.* at 3.

199. Id. at 51.

200. See id.

201. See id. at 34 n.88, 41 n.103 (citing two articles pertinent to the standard of care in this context: Clark C. Havinghurst [sic], Altering the Applicable Standard of Care, 49 LAW & CONTEMP. PROBS. 265, 274-75 (1986) ("arguing that patients should have room to choose the physician standards they feel are most appropriate at an early point in their insurance transaction"), and Jonathan J. Frankel, Note, Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures, 103 YALE L.J. 1297 (1994) ("proposing to reform medical malpractice laws to allow variations in the standard of care").

202. Edward B. Hirshfeld, Commentary, Should Ethical and Legal Standards For Physicians be Changed to Accommodate New Models for Rationing Health Care?, 140 U. PA. L. REV. 1809, 1845-46 (1992).

203. Hirshfeld may have subsequently changed his 1992 proposal, as evidenced by his announcement of the AMA's position in 1993: "[O]ut of respect for the evolution of medicine, the AMA is concerned that making a set of practice guidelines mandatory standards of care would stifle innovation and the dissemination of medical advances." Edward Hirshfeld, Use of Practice Parameters as Standards of Care and in Health Care Reform: A View from the American Medical Association, 19 J. QUALITY IMPROVEMENT 322, 323 (1993).

204. See American Academy of Physical MEDICINE AND REHABILITATION, ADAPTING TO A MANAGED CARE WORLD 33 (1995) (listing managed care impingement on critical decision-making as including "the degree of follow-up care that can be ordered without prior approval;" "the range of services that can be provided in the current visit;" "the latitude in prescribing medications;" and the freedom to admit patients to hospitals, keep patients hospitalized, utilize ancillary services, and refer patients for subspecialty care).

205. Any similarity to specific persons or actual events is purely coincidental.

206. See generally JAMES M. SCHIBANOFF, HEALTH CARE MANAGEMENT GUIDELINES 2 (1999) (published by Milliman & Robertson, Inc., a business/accounting firm, this book purports to "provide a reasonable approach to implementing health care management").

207. See id. at 3 (listing the names of twelve physicians and six registered nurses who participated with the formulation of the published medical care guidelines. the exception With of input from university-affiliated pediatricians, there is indication of university no any involvement, nor any listing of backgrounds and qualifications.).

208. See id. at 80 (publishing managed care guidelines with stated goal of having patients stay only three days after hip replacement surgery, with no elaboration on the numerous variables/co-morbidities that could influence and extend the need for continued hospitalization). Interestingly, this book includes disclaimer from the publishers, entitled "M & R Disclaimer," including statements that the company "does not warrant that the guidelines are free from all errors and omissions. M & R disclaims all express and all implied warranties.... As the author and publisher of this publication, Milliman & Robertson is not involved in providing medical services or dispensing medical advice. Milliman & Robertson disclaims any and all liability arising out of the information provided in this publication." Id. at 2.

209. This text is quoted from an actual hospital memorandum on file with author. The name of the hospital has been omitted for reasons of confidentiality.

210. See 42 C.F.R. § 409.33 (2001) (listing criteria required for continuation of skilled nursing and rehabilitation services under the Medicare program).

211. See 2 CAMPBELL'S OPERATIVE

ORTHOPAEDICS 2324-25 (Allen S. Edmonson & A.H. Crenshaw eds., 6th ed. 1980) (listing potential postoperative complications after hip surgery, including infection and pulmonary embolism).

212. See generally Sage, supra note 3.

213. See Carl Giesler, Managers of Medicine: The Interplay Between MCOs, Quality of Care, and Tort Reform, 6 TEX. WESLEYAN L. REV. 31, 59 (1999) (stating that "[o]nly tort liability will force MCOs to incorporate the socially determined standard of care levels their medical service decisions. into Currently, managed care consumers bear the cost of sub-standard care stemming from MCO treatment decisions. Tort law would make MCOs suffer the consequences of their decisions that impinge on medical care, thereby transferring the costs of substandard care. Accordingly, **MCOs** would have to incorporate those costs in their calculations of whether the benefits of particular treatment justified its expense."). Id. at 59.

214. Barbara A. Noah, The Managed Care Dilemma: Can Theories of Tort Liability Adapt to the Realities of Cost Containment?, 48 MERCER L. REV. 1219, 1251(1997)(advocating a "cost-defense" for tort actions against hospitals and managed care organizations/physicians, claiming that the cost to society should be weighed as a factor when determining whether a given treatment should or should not have been provided).

215. Id.

216. Frankel, *supra* note 201, at 1327 ("This would require a legal regime that allowed beneficiaries and insurers to bargain over the duty of care in the insurance contract and that encouraged courts to defer to that bargain. Plan beneficiaries could establish a more restrictive standard of care (or even a more generous one, should they be willing to pay for it) through contract language that either explicitly defined the decision rule to be applied in cases alleging negligent medical injury or made reference to a set of medical guidelines or practice protocols as a way of defining the procedures that a physician is obligated to provide to a given patient.").

217. Surprisingly, a recent ethics journal article advocated a business-like standard of care (reasonableness standard) for primary care physicians in managed care settings, yet failed to explore the issues of true patient knowledge and agreement. See Bernard Friedland, Managed Care and the Expanding Scope of Primary Care Physicians' Duties: A Proposal to Redefine Explicitly the Standard of Care, 26 J.L. MED. & ETHICS 100-12 (1998). In a commentary reply that rejected Friedland's proposal, Gerard Hickson noted: "Patients would probably like to know [if] their physicians will be held to a lower standard for a given procedure...[y]et experience with patients' understanding of the fine print does not suggest that informed decision-making will result." See Gerard Hickson, Commentary: Don't Let Primary Care Physicians Off the Hook So Easily, 26 J.L. MED. & ETHICS 113, 114 (1998) (advocating an approach "for all parties engaged in health care services delivery, including physicians, hospitals and payers, to share risk for any adverse outcome"). Hickson, however, expresses faith in the "productive setting of offices of quality improvement" of hospitals and managed care organizations, a faith that some physicians may view as misguided the presence potentially given of corrupting business interests. See id.

218. See SCHIBANOFF, supra note 206, at 196-97 (publishing managed care guidelines with the stated goal of keeping hospital stays for heart attack victims to just three days); see also New York Evening News Report (ABC television broadcast, Mar. 14, 2001). A press conference was called by an attorney for thirty-eight physicians who received notices from their hospital that their patients' average length-of-stay was considered unacceptably long. One such letter shown on the broadcast indicated that a cardiovascular surgeon's patients exceeded the average stay by 1.44 days. The physicians were advised to submit a written plan to the hospital for reducing their patients' length-of-stay, or risk losing their hospital privileges. A surgeon with more than fifteen years experience lamented that he was only trying to treat his patients with necessary care, to make certain they were well enough to go home before writing a discharge order.

219. Joseph Azzolina, Hospital Stay Prompts Plans for Study of How HMOs Can Be Overhauled, ASBURY PARK PRESS, Mar. 23, 2001, at A19 (stating that "patients, doctors and hospitals are being taken to the cleaners by the HMOs, while this critical health-care system is being degraded in the process.... Every day we wait to take action is another day a patient is denied proper medical care and doctors and hospitals carry an ever increasing financial burden.... I didn't fully understand the magnitude of their problems until I wound up in the hospital. We must act now before more people are hurt by this unworkable health care system.").

220. See Kenneth R. Pedroza, Note, Cutting Fat or Cutting Corners, Health Care Delivery and its Respondent Effect on Liability, 38 ARIZ. L. REV. 399, 399 (1996) (quoting the New Testament, Matt. 6:24, in reference to physicians trying to serve both patient interests and cost cutting interests).

Justifying Government as the Backstop in Health Insurance Markets

Katherine Swartz, Ph.D.**

Disasters—earthquakes, floods, hurricanes, forest fires, or terrorist attacks—usually bring out selfless behavior as people band together to help those in need. Disasters and our responses to them are reminders that we are in a society together. Unfortunately, for at least the last fifty years, this image of one society has faded when we have tried to work out details for implementing universal health insurance in the United States. A large part of the disagreement about how to achieve universal coverage is over the extent to which we are willing to allow government to intervene in private markets. Yet disasters provide a blueprint for what the role of government might be to help private health insurance markets work more efficiently for everyone and to enable more people to obtain coverage.

Throughout our history, philosophical arguments about the role of government in a market-oriented society have shaped many of our laws and the division of responsibilities among the federal and state governments and the private sector. In the last three decades, economists and, increasingly, politicians have argued that the free market advances economic growth and opportunity more effectively than government policies intended to achieve such goals. This view rests on the widespread belief among American economists that competitive forces yield efficiency in both the production and the allocation of goods and services.¹ Moving from a static to a dynamic context, economists also see free market competition as a strong spur to innovation. As the view has taken hold that competition yields efficiency in markets, policy-makers have paid increasing attention to the way in which government regulation might inhibit competition and incentives for companies in a market to be

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efficient. There is now a widespread belief among economists, policy analysts, and policy-makers that government should intervene in a market only when conditions for competition are not in place, and the market fails to be efficient.

In the case of health insurance, the absence of a competitive market can arise for a variety of reasons. Within a geographic area, there are traditional concerns about monopolies. There are also more subtle concerns involving the role of information. Perfect competition requires that all market participants have perfect information on what is being bought and sold. By contrast, health insurance markets can be plagued by adverse selection-the phenomenon in which people who anticipate high medical care costs will be most likely to purchase health insurance.² One consequence of the possibility of adverse selection is the extensive use of screening mechanisms by insurers to avoid high-risk (potentially high-cost) enrollees. This results in people who are perceived to be high-risk being unable to obtain coverage at affordable premiums, or denied coverage altogether. It also results in inefficiency in the health insurance markets as insurers invest in the non-productive efforts of screening to avoid high-risk people. Such efforts increase the costs of insurance for all who obtain coverage.

The role of government in dealing with disasters provides us with a blueprint for how government might reduce inefficiency in health insurance markets. Insurers almost always judge the risks of large-scale losses in the event of a disaster as too great to insure against, and they then refuse to sell coverage for such possibilities. Earthquake insurance is hard to obtain in areas that are prone to earthquakes, and it is increasingly difficult to purchase insurance for hurricane damage in coastal areas that are subject to hurricanes. But markets for property damage, casualty, and liability insurance exist and are relatively competitive. Why? The answer is that the government (primarily the federal government) has increasingly moved to provide disaster relief, thereby taking responsibility for the worst or highest risks in these markets. Government plays a backstop role in these markets by implicitly (if not explicitly) agreeing to be responsible for a large share of the costs of future disasters. This role enables insurers to cover lesser risks for property damage and liability, thereby allowing the markets for such insurance to function.

Similarly, government could take responsibility for the costs of people with the highest medical care expenses. That is, the government would shift the risk of unexpectedly very high costs from the insurers to the broad base of citizens and corporations from which it gathers general tax revenues. This would enable insurers to offer health insurance for medical care costs below the 98th or 99th percentile of the distribution of all medical care costs, and to be efficient in providing insurance since they would not feel compelled to screen people the way they do now. By backstopping the insurers, the government would ensure that the health insurance market would be accessible to a broader set of people, and would be more efficient, thereby enhancing social welfare.³ Having the government backstop insurance markets so they function more efficiently is similar to government enforcement of laws regarding property rights. Without such enforcement, some markets might not function at all, and others would be markedly less efficient because payments would have to be made to middlemen to enforce a person's rights.

In this Article, I expand on the rationale for government taking on a backstopping role in health insurance markets. I explain why health insurance markets would be more efficient and how social welfare would increase as a result. In Part I, I briefly review the two most frequently cited economic arguments for government involvement with health insurance markets. The argument that government contributes to the efficiency of insurance markets by redistributing the costs of the highest risk individuals builds on the more common argument that government should intervene in markets when they fail to be competitive. In Part II, I discuss why imperfect information creates market inefficiencies. In Part III, I describe how health insurers compete, and why the small group and individual (non-group) health insurance markets are inefficient. In Part IV, I suggest how government might spread the costs of high-risk people, and discuss why the government would reduce inefficiency in the insurance markets if it were a backstop for markets by removing the worst risks.

I. ECONOMIC JUSTIFICATIONS FOR GOVERNMENT INVOLVEMENT IN HEALTH INSURANCE

Economic theory offers two justifications for intervention in the economy.⁴ The first involves redistributing resources to assist poor or otherwise deserving groups of people who are unable to afford goods (like food or health care) that are deemed to be necessities. The second involves redressing causes of market failures—conditions of various kinds that result in a failure to achieve economic efficiency.

A. Redistribution of Resources

Economists are concerned with both economic efficiency and the distributional consequences of markets. When a market yields an allocation of its product to various consumers in such a manner as to be

judged unfair, many economists argue that a redistribution of resources should occur to make the distribution fair. Unfortunately, it is difficult to agree on what is a fair distribution, and even more difficult to agree on why one allocation is better than another. Economics and philosophy intersect when it comes to determining how we may or may not compare different individuals' levels of happiness or welfare, and how we might judge when one distribution of resources is better than another. Most economists believe that different individuals' levels of happiness cannot be compared to each other. This leaves economists in the awkward position of not having a tidy method for declaring one distribution of resources fairer than another. Instead, economists can say only that one group of people benefits or bears the burden of some policy or market outcome. We often observe a redistribution of resources when the public or policy-makers judge it to be unfair that a group within society has a disproportionate share of the benefits or burden.

Most economists argue that such resource redistributions should take place outside the market in order to leave the market's efficiencyenhancing incentives as intact as possible. This argument prefers a direct income transfer like food stamps to a policy of price controls on food. The food stamps do not alter the prices that farmers receive for their products, and they do not cause higher-income people to purchase more food as they might if all food prices were artificially low. The redistributive justification for government involvement with the economy also explains the genesis of Medicare and Medicaid. They are a response to the argument that access to health care should not depend on ability to pay, and therefore government has a responsibility to guarantee financial access to medical care.⁵ Both programs involve redistributing tax revenues from the general population to pay for medical care for people who enroll in the programs.

Although many Americans believe it is unfair that one in six people are without health insurance, there is widespread disagreement about how redistribution of resources might be accomplished so that everyone would have health coverage. There is no clear mechanism for providing health insurance to everyone without hurting the interests of some people, usually the wealthy. This has hampered advocates of expanding health insurance who have relied on the redistribution rationale for government involvement in the economy.

B. Economic Efficiency and Market Failure

The second economics justification for government intervention involves market failure. Historically, markets were said to fail when they were inefficient—a situation that occurs when individuals bear either more or less than the full costs of resources they consume, or fail to receive the full benefits of products they produce. These conditions could arise from any of three general cases:

1. Market Power. A market is controlled by one or several producers who do not compete with each other and who block competition from potential new entrants. For example, a group of radiologists supply all the radiology services in a town and effectively bar any new radiologists from contracting with the town hospitals. In this case, consumers are likely to be charged more than the full cost of services consumed.

2. Negative and Positive Externalities. An individual's action creates a cost (or benefit) for others for which the individual does not pay (or is not rewarded). For example, without environmental regulation, a factory would have little incentive to consider the costs its pollution imposes on others. Without a patent system, an inventive person would have little incentive to develop ideas that could be freely copied.

3. Public Goods. Goods like public health or national security, which, once created, can be universally consumed and cannot be restricted to only the individuals who paid for the good.

In the last thirty years, these three classical reasons for market failure have been joined by a fourth—asymmetric information. Asymmetric information was the subject of the 2001 Nobel Prize in Economics. The three prize recipients (Joseph Stiglitz, George Akerlof, and Michael Spence) made explicit another assumption of the competitive model—that people have full information about what they are buying or selling—and showed the consequences when that condition is not met. Asymmetric information is increasingly cited as a barrier to competitive markets and therefore a reason for market failure in health care and health insurance markets.

Debates about whether government should intervene in markets have almost always turned on the interpretation of evidence for and against the presence of one or more of these four causes of market failure. Government interventions in markets are generally in the form of regulations to prohibit or require certain activities, or taxes and subsidies to alter the relative prices of products. The intent of these actions is to alter the constraints and incentives that producers and consumers face in a market so the market becomes more competitive and, therefore, more efficient.

II. ASYMMETRIC INFORMATION AND HEALTH INSURANCE

The focus of this Article is how the government might address asymmetric information's effects in health insurance markets, and therefore it is important to understand why imperfect information causes markets to fail to be efficient. In general, when consumers and producers do not have the same information, the information asymmetry favors producers because consumers have difficulty obtaining a great deal of information. For example, when consumers do not purchase a good frequently (such as a car), it is difficult to know about all the price and quality differences among cars and among car dealers.⁶ Public policies often have been designed to provide information to consumers so as to redress the information asymmetry between consumers and producers. In the case of cars, most states now require car dealers to disclose the cost of the car to the dealer and the additional mark-ups that the dealer has added.

In health insurance markets, the information asymmetry generally favors consumers. Consumers know far more about why they wish to purchase health insurance than indemnity insurers or managed care organizations (hereafter collectively referred to as carriers) can ever know. Carriers know from experience that people who know or suspect they will have expensive health care needs in the coming year are more likely to apply for insurance coverage than are those who think they are quite healthy. This creates an adverse selection problem because carriers do not have full information to correctly distinguish between low-risk and highrisk applicants. As a result, explained more fully in the next Part, the carriers compete in terms of mechanisms to screen out high-risk people. This type of competition yields inefficiency in health insurance markets because the carriers spend resources on activities that do not produce insurance per se. In addition, the selection activities limit the access to health insurance for those individuals perceived to be high-risk, as compared to their lower-risk contemporaries.

III. HEALTH INSURANCE MARKETS AND HOW CARRIERS COMPETE

In the United States, the majority of people obtain health care coverage through employers. Approximately 64% of the population (of all ages) have employer-sponsored group coverage.⁷ Those with such coverage pool their own risks of high medical care costs with other individuals covered by the same employer. Because almost everyone in large employer groups participates in the employer-sponsored health insurance plan, there is only a small proportion of each group that is likely to have

unexpectedly high medical expenses. But people who do not have access to such pooling of risks—the uninsured and the people who obtain individual coverage—face insurance markets in which adverse selection is a major problem.

Health insurance is sold in the United States in three interconnected markets. We can loosely distinguish between large employer group, small group, and individual (non-group) insurance markets. Some carriers actively sell coverage in all three markets, but most do not. More often, we observe large carriers selling coverage to large employer groups, with some of the major large carriers selling policies in the small group and individual markets. Smaller carriers sell policies almost exclusively in the small group and individual markets. In addition to these three types of markets, every state (and the District of Columbia) regulates how insurance is sold within its borders. The states have different regulations governing facets of insurance ranging from what benefits must be covered by insurance policies to how rates are determined to requirements about financial reserves that the carriers must hold. As a result, there are fifty-one different sub-markets within each of the three distinct markets. Many carriers, particularly smaller carriers, offer policies only in those states with similar regulations so they do not have to keep track of, and respond to, many regulatory changes. One consequence of this is that in the individual markets in 1997, the number of carriers selling individual policies ranged from two or three (in Delaware, Idaho, and Alaska) to more than forty (in New York and Texas).⁸ New York's relatively large number of carriers selling individual coverage is due to the requirement that all HMOs sell individual coverage. In 1997, just under 700 carriers sold individual policies in the United States; by comparison, 2,450 carriers sold policies in the large and small group markets.⁹ In spite of this difference, the individual and group markets are characterized by a small number of carriers having at least half of the total number of policies sold in each type of market in each state.¹⁰

Large employers have avoided state regulations and state taxes on health insurance by self-insuring (or self-financing) their employees' health care costs. The Employees Retirement and Income Security Act of 1974 (ERISA) exempts self-insured employers from state regulations and taxes on policies sold within a state. Most self-insured employers pay a fee to a third-party administrator (almost always a carrier) to administer the claims from medical care providers, and the employees are usually unaware that the third-party administrator is not technically their insurer as well.

Health coverage is sold and priced quite differently in the three types

of health insurance markets (ignoring for the moment the fifty-one different jurisdictions' regulations). The selling practices and pricing differences largely reflect the extent to which carriers fear adverse selection in each of the markets. In the large group market, adverse selection at the group level is uncommon since almost all employees of a large employer enroll for coverage. However, when an employer offers a choice of plans, those carriers that are the choice of a small proportion of the group may be concerned about adverse selection.¹¹ Employees and their dependents in large group plans pay average premiums based on the total expected costs of the group; a particular person's expected medical care costs are not factored into the premium he or she pays. Usually, the employer also negotiates with several carriers as to the out-of-pocket cost sharing and benefits covered, and trade-offs between these and the premiums.¹²

Small groups (typically, groups with less than fifty employees) and individuals face very different markets. Per policy premiums are substantially higher in these markets; it is not unusual to find premiums for single or family policies to be more than twice as expensive for small groups or individuals than for large groups.¹³ Carriers' fear of adverse selection among applicants in the small group and individual markets motivates the carriers' behaviors. Insurers fear adverse selection because it causes them to underestimate premium revenues needed to cover expenditures and thus to risk substantial financial losses. To avoid adverse selection, many carriers adopt selection mechanisms to screen out applicants who they suspect will use expensive medical care.¹⁴ Such mechanisms include medical underwriting practices,¹⁵ refusing to issue or renew a policy, excluding coverage of services for pre-existing medical conditions, and differentiating their policies from their competitors' by generously covering some types of services (e.g., preventative), but limiting coverage of other services (e.g., substance abuse treatment¹⁶).¹⁷

Thus, competition in insurance markets, especially the small group and individual markets, focuses on how well carriers use mechanisms to identify which firms or individuals might be high-risk versus low-risk. When carriers are permitted to set different premiums for people who the carriers predict will have different probabilities of using expensive medical care, they compete in large part in terms of the accuracy of their models for predicting a person's (or firm's) medical expenses.¹⁸ Different carriers will then price their health insurance policies to people and small firms based on the individual's or firm's expenditures predicted by each carrier's actuarial model. Usually, the models are used to determine how the premiums might be "underwritten" for particular individuals or firms. That is, if a small firm is predicted to have a high risk of high medical expenses in the next year because several people in the group had high expenses in the last year, the carrier may agree to offer insurance only if the firm pays a substantially higher premium in the coming year. The additional premium amount underwrites the basic premium for the policy.

Underwriting principles might also cause a carrier to deny coverage completely or to exclude coverage for a condition to a group or person on the basis of information known by the carrier. Most states allow exclusion of coverage for a pre-existing condition (such as cancer, osteoarthritis, or allergies) for a limited time period—typically twelve months. As a result, carriers more often simply deny an application if a person has had serious conditions, such as angina or a myocardial infarction.¹⁹ In some states, underwriting of premiums is not permitted because it is viewed as a selection mechanism that discriminates against people who are perceived to have high risks of expensive medical care. When underwriting is not permitted or its use is restricted, carriers turn to other selection mechanisms to avoid insuring high-risk people.

A frequently used mechanism for separating high- and low-risk applicants consists of differentiating the benefits (or medical services) covered by a policy. If a carrier is able to identify a health care benefit that is particularly attractive to low-risk people but not high-risk people, then it can design policies that cause people voluntarily to reveal whether they are likely to be low- or high-risk. Thus, for example, if a person knows that cancer runs in his or her family—which the carriers do not know—the person might choose a policy that has high upper limits on covered expenses, provides for cancer screening tests, and includes first-rate cancer centers in the list of providers. By choosing such a policy, the person is revealing information to the carrier regarding his or her risk expectations. Carriers have invested in substantial efforts to understand how differences in benefits packages can be used to attract low-risk people to some policies and high-risk people to other policies.

Carriers also have developed monopolistic market niches in the small group and individual markets as another mechanism for avoiding adverse selection.²⁰ In the individual markets, for example, some carriers specialize in marketing to individuals who have left the armed services; others specialize in policies attractive to very small firms of professionals (e.g., lawyers or financial advisors) or only to individuals who are self-employed. As a result, few carriers in a state market actively compete for business among all consumers seeking individual policies, and people who carriers perceive as high-risk have few, if any, options for obtaining health insurance.²¹

The differences in states' regulations of the insurance markets within their borders permit greater or lesser use of these mechanisms or different combinations of the strategies to avoid insuring high-risk people. States that have attempted to block carriers' use of such preferential selection mechanisms, particularly in the small group or individual markets, have almost always set up regulations that block the use of only one or two of these mechanisms. State regulations, for example, might mandate that all policies sold in the state must cover substance abuse treatment to inhibit carriers' abilities to avoid people who want coverage for substance abuse. Some states have enacted regulations requiring carriers to accept any applicant ("guaranteed issue") so a carrier cannot turn down an applicant it views as high-risk. For example, carriers in the individual insurance markets in Washington, New York, and New Jersey are required to issue policies to any applicant regardless of the applicant's health status, age, or place of residence. But, of course, if a state has only one or two of these regulations in place, the carriers can use other mechanisms that are not proscribed to accomplish the same objective. A common example is when a state requires carriers to accept any applicant, but does not also have a regulation governing the way in which premiums can be set, we observe what should be an expected outcome-high-risk people are indeed offered coverage, but at an extraordinarily high premium. Similarly, when states require community rating of premiums (say, in the small group insurance market), but do not standardize the benefits to be covered in policies sold in the market, carriers can use differences in what benefits are covered under different policies to try to separate employers with large fractions of high-risk employees from those with large fractions of low-risk employees.

In summation, the information asymmetries in health insurance markets, particularly the small group and individual markets, cause them to be inefficient. Carriers compete with each other not in terms of producing insurance per se at the lowest possible cost, but in terms of insuring as high a proportion of low-risk people as possible to keep costs low. Thus, the usual competitive market forces that cause producers to seek profits by reducing their costs of production and increasing market share have been altered by the fear of adverse selection in insurance markets. In insurance, carriers seek to minimize their risk of unexpected high costs by competing to have very high shares of low-risk people among the people they insure. The competition among carriers consists of trying to do better than other carriers at selecting low-risk people, which involves efforts that do not contribute to producing insurance. The costs of creating and using selection mechanisms are a measure of the inefficiency that exists in health insurance markets.

IV. GOVERNMENT AS DISTRIBUTOR OF RISK

The economy can produce more when risks in markets are reduced by actions that pool risks and/or shift risk to people who are willing to bear the risk in exchange for a payment. Insurance markets that might be formed to address risk—such as the risk of unexpectedly high medical care costs—will form and be efficient if the risk is truly random and unrelated to any observable characteristic of a person or entity seeking insurance. But as we have seen, if there are characteristics associated with higher risk, a potential insurance market is faced with an information problem that manifests itself as adverse selection. When adverse selection occurs, a market will be inefficient because of the efforts spent trying to detect the information—or a market can fail even to form. However, if the government acts to cover the costs of the worst risks, an inefficient market can become more efficient, and a non-functioning market can be stimulated to form. In particular, if the government removed the risk to carriers of very high-cost people, carriers would not have to spend as much on selection mechanisms to avoid insuring high-risk people.

The government has two options for shifting the risk of very high-cost people from carriers: (1) provide financial coverage outright; or (2) take on the role of reinsurer. Both options rely on the government's ability to tax a broader segment of the population than just those individuals with coverage through the individual or small group markets.

A. Provide Insurance Coverage

Medicare, Medicaid, and the Veterans Administration's health care are all examples of government-provided financial coverage of health care costs. As noted earlier, the establishment of Medicare and Medicaid was justified in part because they redistribute resources to deserving groups of people: the elderly, disabled, and very poor. Medicare was also justified because disabled and senior citizens found it virtually impossible to obtain health insurance prior to 1965 at a price they could afford. People who have served in the armed forces of the United States are covered by the health care program of the Veterans Administration (VA) for medical problems caused by their active duty. The VA was created in part to provide efficacious medical care to people who might have injuries or problems that the civilian population generally does not have. Having centers of expertise in VA hospitals is both more efficient and more effective than relying on physicians and hospitals scattered across the country with little experience with such problems. Additionally, without the presence of the VA, carriers might charge very high rates to veterans and/or refuse to cover medical services that might be related to injuries or medical problems incurred in the armed forces. These three government programs provide coverage to specific groups of people who have higher than average probabilities of needing high-cost medical care, and consequently would have difficulty obtaining health insurance in the private markets.

The government could provide similar health insurance programs to other identifiable groups of people who are perceived as very likely to have high expenses and therefore have trouble obtaining private coverage. *Ex ante*, however, it is difficult to identify other "targetable" groups of people who are likely to have high medical expenses—which is why the carriers spend an enormous amount of effort trying to avoid covering high-risk people. However, the government could target people for programs *ex post*, perhaps by identifying individuals with medical expenses that put them in the top 1% or 2% of the distribution of medical expenses of the entire population. Once a person was identified as being "high cost," the government would pay all of the person's medical expenses. Such a government sponsored "high-cost" program would drastically reduce carriers' incentives to spend resources on selection mechanisms.

B. Government as Reinsurer

The other option for the government's role in health insurance markets is to become a reinsurer for carriers that have covered high-cost people. That is, the government could pay a portion of the costs of those individuals whose total annual medical costs exceed some threshold-say, \$30,000-or an amount that places a person's medical expenditures above the 98th or 99th percentile of the entire population's distribution of medical expenses. Carriers often purchase reinsurance to protect themselves from the risk that an insured's claims will exceed \$50,000.²² Private reinsurance reduces a carrier's exposure to the risk of high-cost enrollees; the costs of the reinsurance fall on the other individuals obtaining coverage from the carrier. These costs, in addition to the higher premiums due to high-cost enrollees, fall totally on a carrier's enrolleesreinforcing carriers' fears that they will lose low-cost enrollees if such costs continue to rise. Instead, if the government acted as the reinsurer for the high-cost claims, the costs of the reinsurance and the higher expenditures being reinsured would be shifted from the carrier's enrollees. Carriers would then have far less incentive to avoid high-risk people.

Reinsurance usually requires the original insurer (the carrier) to bear some portion of the costs above the threshold so the carrier will still have an incentive to continue to manage the health care of high-cost people. It would be important to retain this incentive if the government were to reinsure the very high medical care expenses. Moreover, the government could cover either a portion of the costs above the threshold that causes a person's expenses to be eligible or a portion of all of the costs. In either case, the share of costs that the government would cover also could vary over different levels of expenditures. For example, the government could cover 80% of the costs above the eligibility threshold up to two times the threshold, and then 90% of the costs above that.

Either of the options discussed above would curtail the use of selection mechanisms to avoid high-risk enrollees and would, therefore, make the market more efficient. These changes would immediately provide what economists call a "welfare" gain to everyone who purchases health insurance in the small group or individual insurance markets since the premiums for insurance would decline in proportion to the reduction in use of selection mechanisms.²³ Moreover, high-risk people who currently cannot obtain coverage from all carriers also would benefit because carriers would no longer deem them undesirable. High-risk people would have greater access to carriers and policies in insurance markets.

The welfare gains caused by the increased efficiency in the insurance markets brought about by either of the government options are not "free," of course. Both options require government revenues to pay all or some of the medical care costs of the designated high-cost people. Three major types of taxes could be used to pay these high medical costs: (1) payroll tax; (2) income tax; or, (3) head tax. Moving from a payroll to income to head tax involves an expanding subset of the population, but each tax has different impacts on the after-tax income distribution. Payroll taxes are a percent of wages and salaries, and are paid only by people who are working. Income taxes apply to all forms of income (e.g., salary, rental property income, and investment earnings) and are generally more progressive than either a payroll or head tax since higher income people are taxed at higher rates than lower income people. A head tax is independent of income and applies to every person in the country regardless of age. In addition, all of the revenue sources for the states' and federal governments' general revenue funds-including fines or settlement agreements paid by corporations (e.g., the tobacco settlement funds) and excise taxes not dedicated to other purposes—could be used if the general revenue funds were tapped to finance high-cost medical expenses.

A political advantage of using the income tax and sources of revenues for the general revenue funds is that they do not require implementation of a new tax to pay for either a new insurance program for high-cost people or a reinsurance fund to pay carriers for high-cost claims. On the other hand, when a program is competing for general revenue funds along with high-visibility government programs—such as education, highway maintenance and construction, or homeland security—then it is vulnerable to budget-cutting pressures. This is particularly true for programs that benefit everyone but may appear to assist only a small number of people, in this case those individuals with high-cost claims. The argument has to be made that both of the government options for highcost individuals increase the efficiency of insurance markets, thereby providing benefits to everyone.

Implementing an institutional structure to permit the government to take responsibility for the health care expenses of the very high-cost individuals would also require some standardization of health policies sold in the small group and individual markets. Standardizing the benefits covered by policies would make it possible to compare medical expenditure patterns of people and then to identify those people who have the very highest medical expenses. Without such standardization, it would be quite difficult to know whether a person had high expenditures because of a very generous insurance policy as opposed to being quite ill.

Finally, by providing either total coverage or reinsurance for very high medical care costs, the government would provide stability to health insurance markets. Stability contributes to efficiency in markets because people are able to make choices about purchasing insurance with less uncertainty about future premiums. When carriers find themselves in a spiral of rising costs due to adverse selection and falling enrollment of low-risk people, they often raise premiums to try to cover their anticipated losses. But rapid premium increases cause lower-risk people to drop their coverage, which further exacerbates the imbalance of costs and revenues and often leads to a death spiral for a particular policy or carrier. A market that is destabilized by rapidly rising premiums or loss of carriers will not attract lower-risk people to purchase coverage, and ultimately will fail to function.²⁴

Thus, if government uses its power to redistribute the risk of very high medical care costs from carriers to broader sub-groups of the population, it would increase efficiency in health insurance markets—particularly the small group and individual insurance markets. The increase in efficiency would enable more people to obtain health insurance. Premiums would be reduced because carriers would reduce their efforts to identify high-risk people who they do not want to insure. As a result, relatively low-risk people would be more likely to obtain and retain coverage. Higher-risk people, who currently have great difficulty finding carriers willing to insure them, would have more choice of policies and carriers since there would be sharply reduced incentives for carriers to avoid higher-risk enrollees.

CONCLUSION

When markets fail, economic theory tells us that government should intervene in the market so as to increase efficiency. When risk is present in markets, such as health insurance markets, market failure can be especially likely because of information asymmetry and the potential for adverse selection. Risk also can prevent markets from forming. If government acts to take care of or remove the worst risks in such markets, the inefficiency in the markets would be greatly reduced, and markets that otherwise could not even start up would be able to function.

There are precedents in other markets with risk where the federal government has taken responsibility for the worst risks, thereby enabling markets to function and grow. Reinsurance for catastrophes exists because there has been a history (including the response to the terrorist attacks of September 11, 2001) of government stepping in to pay large fractions of the costs of catastrophes. Indeed, the creation of the Federal Emergency Management Agency (FEMA) in 1978 formally acknowledged the federal government's role in assisting with recovery from catastrophes. The secondary mortgage market, which enables lenders of mortgage money to replenish their capital, exists because the federal government has responsibility for the worst risk mortgages. The Federal Housing Authority (FHA) and the VA shifted the risk of default from mortgage lenders to the federal government for people who otherwise would not have qualified for mortgage loans. Moreover, the FHA mortgage insurance and the VA mortgage guarantee program set minimum standards for what properties were eligible for mortgages and what types of financial information were needed from borrowers. This standardization of information permitted mortgages to be resold on a national basis because standardized information made it easier for lending institutions that were not local to perform due diligence investigations of mortgages that were offered for resale in the secondary mortgage market. It is unlikely that either the reinsurance market or the secondary mortgage market would function without the government backstopping them by covering the worst risks.

Health insurance markets similarly need the government to spread and redistribute the costs of those individuals with the highest medical expenditures. If the government were to take responsibility for the highest cost people, carriers in the small group and individual insurance markets would spend less on efforts to avoid enrolling these individuals. This would reduce the rates for health insurance faced by people who purchase insurance in these markets and enable a much larger set of people to obtain health coverage—all of which would increase economic welfare for the country.

References

1. Roughly speaking, efficiency is achieved in a market when no individual can be made better off unless another individual is made worse off.

2. Michael Rothschild & Joseph Stiglitz, Equilibrium in Competitive Insurance Markets: An Essay on the Economics of Imperfect Information, 90 Q. J. ECON. 629 (1976); see also Harold S. Luft, Potential Methods to Reduce Risk Selection and Its Effects, 32 INQUIRY 23 (1995); Joseph P. Newhouse, Cream Skimming, Asymmetric Information, and a Competitive Insurance Market, 3 J. HEALTH ECON. 97 (1984); Mark V. Pauly, Is Cream Skimming a Problem for the Competitive Medical Market?, 3 J. HEALTH ECON. 88 (1984).

3. "Social welfare is maximized by the joint pursuit of efficiency [in the production of goods and services in their allocation] and social justice." NICHOLAS BARR, THE ECONOMICS OF THE WELFARE STATE 279 (3d ed. 1998). Unfortunately, a definition of social justice is less easily agreed to by economists and others. The stumbling block is that such definitions involve value judgements.

4. Nicholas Barr, Economic Theory and the Welfare State: A Survey and Interpretation, 30 J. ECON. LITERATURE 741, 743 (1992).

5. The State Children's Health Insurance Programs (SCHIPs), implemented in 1998, have a similar justification for existence.

6. Consumer Reports, published by Consumers Union, is perhaps the most widely known consumer-based magazine and newsletter that provides information about infrequently purchased items. State agencies' web sites (particularly state agencies that oversee health insurance) often contain information for consumers about available policies and premiums.

7. U.S. CENSUS BUREAU, CURRENT POPULATION SURVEY tbl.1 (2001), available http://www.census.gov/hhes/hlthins/ at hlthin00/dtable1.html. The estimates by type of coverage are not mutually exclusive because people can be covered by more than one type of health insurance during the year, and in some cases at the same time (for example, some people have both Medicare and Medicaid coverage). Thus, 8% of the population have non-group private coverage, 13% have Medicare, 10% have Medicaid, 3% have military coverage (CHAMPUS/VA), and 14% are uninsured. Id.

8. DEBORAH J. CHOLLET ET AL., MAPPING STATE HEALTH INSURANCE MARKETS: STRUCTURE AND CHANGE IN THE STATES' GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS 1995-1997, 20 tbl.7 (Academy for Health Services Research and Health Policy 2000).

9. Id. at 5 tbl.1.

10. Id. at 9-17.

11. Thomas C. Buchmueller & Paul J. Feldstein, The Effect of Price on Switching Among Health Plans, 16 J. HEALTH ECON. 231 (1997); David M. Cutler & Sarah J. Reber, Paying for Health Insurance: The Trade-Off Between Competition and Adverse Selection, 113 Q. J. ECON. 433 (1998).

12. Two frequently cited issues in health insurance are adverse selection and moral hazard. Adverse selection is a result of information asymmetry. Moral hazard, on the other hand, is caused by insurance itself—insurance reduces the effective price to an individual and masks the true cost of an individual's action. Thus, a person with health insurance may engage in riskier behavior that increases health care use
(perhaps skiing on black diamond trails when he is not an expert skier) than he would if he faced the full costs of the behavior. More commonly, when health insurance pays for most of the costs of a medical visit, people have an incentive to see a physician more often than if they paid the full cost of the visit. Such insuranceinduced demand for health care causes society to spend more on medical care than would be the case if people paid the full cost of the medical care. Economists call this additional expenditure a welfare loss because it is money that is not available to be spent on other goods or services that have greater marginal value than what it costs to produce them. Moral hazard can be reduced by increasing the cost-sharing required of people when they obtain health care, particularly health care that is of a non-emergency nature.

13. Economists break an insurance premium into two parts: a person's expected medical care costs and a "loading fee." The loading fee encompasses marketing and administrative costs (such as processing medical claims and enrolling a person in a policy), and a payment to the insurer for bearing the risk that the person might have unexpectedly high medical care costs. In large employer-sponsored groups, the risk that any one person might have unexpectedly high medical costs is pooled with many other people in the group. This reduces the risk faced by an insurer, so that the payment portion of the loading fee for the insurer bearing risk is reduced for large groups. Loading fees as a percent of the premium for large groups have been estimated to be about 5%. In contrast, the loading fees are estimated to be about 30% to 40% of premiums for policies sold to small groups and 60% to 80% for policies sold in the individual market. CHARLES E.

PHELPS, HEALTH ECONOMICS 347 tbl.10.3 (2d ed. 1997). The much larger loading fee in these markets is due primarily to the smaller numbers of people with whom a person's risk of having unexpectedly high medical care costs can be shared, and concern that the other people enrolled in these markets are higher-risk people.

14. DEBORAH J. CHOLLET & ADELE M. HENRY J. KIRK. THE KAISER FAMILY FOUNDATION, UNDERSTANDING INDIVIDUAL HEALTH INSURANCE MARKETS: STRUCTURE. PRACTICES, AND PRODUCTS IN TEN STATES (1998); Newhouse, supra note 2; Joseph P. Newhouse, Is Competition the Answer?, 1 J. HEALTH ECON. 110 (1982); Joseph P. Newhouse, Reimbursing Health Plans and Health Providers: Efficiency in Production versus Selection, 34 J. ECON. LITERATURE 1236 (1996); Katherine Swartz & Deborah W. Garnick, Adverse Selection and Price Sensitivity When Low-Income People Have Subsidies to Purchase Health Insurance in the Private Market, 37 INQUIRY 45 (2000) [hereinafter Adverse Selection and Price Sensitivity]; Katherine Swartz & Deborah W. Garnick, Can Adverse Selection Be Avoided in a Market for Individual Health Insurance?, 56 MED. CARE RES. & REV. 373 (1999) [hereinafter Avoiding Adverse Selection in Individual Health Insurance]; Katherine Swartz & Deborah W. Garnick, Lessons from New Jersey, 25 J. HEALTH POL., POL'Y & L. 45, 46 (2000) [hereinafter Lessons from New Jersey].

15. Medical underwriting (sometimes called experience rating) is the process by which insurers determine as best they can each individual applicant's expected medical care costs. The process usually entails asking questions about the applicant's history of health care use, asking whether the applicant or a family member has any of a list of specific medical conditions, and sometimes performing a medical exam. Thus, if a person has poor actuarial health status, underwriting practices would yield high premiums. When carriers set premiums for policy renewals, medical underwriting can yield high premiums for people who have had expensive medical care in the previous six to twelve months, or an outright denial of renewal of coverage. In contrast. community rating is when everyoneregardless of age, sex, occupation, and other characteristics-is charged the same premium for the same policy. Some states permit what is termed modified community rating, which permits different rates by factors such as geographic area of residence, age, and sex. Community rating is always for a particular type of plansingle, husband-wife, adult plus child(ren), and family.

16. Richard G. Frank et al., Solutions for Adverse Selection in Behavioral Health Care, 18 HEALTH CARE FIN. REV. 109 (1997); Deborah A. Stone, The Struggle for the Soul of Health Insurance, 18 J. HEALTH POL., POL'Y & L. 287 (1993).

17. Observers of insurance markets often assume that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) has restricted these selection practices in the individual insurance market. In fact, HIPAA provides portability of coverage and protection from some selection practices for only a limited group of statutorily defined "eligible individuals," people who had prior group coverage for at least eighteen months, have exhausted Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) benefits, and lack current access to group coverage or public programs. Len M. Nichols & Linda J. Blumberg, A Different Kind of "New Federalism"? The Health Insurance Portability and Accountability Act of

1996, 17 HEALTH AFF., May-June 1998, at 25, 31-32. HIPAA does not prohibit carriers from applying selection practices to the great majority of individuals who seek coverage in the individual health insurance markets. A related statute is COBRA, which required firms of twenty or more employees to offer access to the firm's group insurance policy following а "qualifying event" for up to eighteen months for a work-related event, and thirtysix months for a family-related event. Workrelated events include termination of employment; family-related events include loss of dependent coverage due to divorce or death of an insured worker. People who qualify for COBRA coverage pay а premium not to exceed 102% of the sum of the employer and employee shares of the premium. Patrice Flynn, COBRA Qualifying Events and Elections, 1987-91, 31 INQUIRY 215, 216 (1994).

18. These models are generally known as actuarial models because they are based on actuarial tables of likelihoods using different amounts of medical care by many different demographic and socio-economic characteristics as well as health status and prior use of health care. Applicants in both the small group and individual markets generally have to respond to questionnaires about their health status, use of medications and medical care in the past, and health risk behaviors (such as smoking and recreational activities). It is not unheard of for small groups to be offered coverage for most but not all of the members of the group-with the rejected members being denied coverage because of carrier fears that such people will be costly users of medical care.

19. CHOLLET & KIRK, supra note 14, at 43-44.

20. Lessons from New Jersey, supra note

14; Adverse Selection and Price Sensitivity, supra note 14.

21. KAREN POLLITZ ET AL., THE HENRY J. KAISER FAMILY FOUNDATION, How ACCESSIBLE IS INDIVIDUAL HEALTH INSURANCE FOR CONSUMERS IN LESS-THAN-PERFECT HEALTH? (2001). Also, in a General Accounting Office (GAO) survey of seven states' individual health insurance markets, the vast majority of the companies did not actually sell individual insurance to any applicant. Instead, these companies had a book of business of individual policies that were conversions from group policies or were restricted to people who were self-employed and belonged to associations of similarly self-employed people. GAO, PRIVATE HEALTH INSURANCE: MILLIONS RELYING ON INDIVIDUAL MARKET FACE COST AND COVERAGE TRADE-OFFS. (1996), GAO/HEHS-97-8 available at http://www.gao.gov/.

22. Private correspondence with confidential source (notes on file with author).

23. Welfare gain occurs when people have more choice of goods and services in the economy, more income, or goods and services are thought to be distributed more fairly. *See also supra* text accompanying notes 3 and 12.

24. Lessons from New Jersey, supra note 14.

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CASE STUDIES

Question:

Should the federal government fund human embryonic stem cell research?

On August 9, 2001, President George W. Bush announced his decision to provide federal funding for research involving human embryonic stem cell lines already in existence on that date. Authors from various disciplines were asked to consider the President's decision. Their responses follow.

RESPONSES

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Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules

Samuel B. Casey, J.D.* and Nathan A. Adams, IV, J.D., Ph.D.^{+‡}

The being that is now you or me is the same being that was once an adolescent, and before that a toddler, and before that an infant, and before that a fetus, and before that an embryo. To have destroyed the being that is you or me at any of these stages would have been to destroy you or me.¹

The debate about whether to federally fund human embryonic stem cell research is at root a controversy about the legal status that should be accorded the human embryo. The undisputed, scientifically verifiable facts agreed to by even the most liberal proponents of human embryonic stem cell research are that (1) the embryo is living and genetically unique;² (2) the embryo is human and capable of developing into an adult;³ and (3) derivation of human stem cells from embryos terminates them.⁴ Although philosophical and political disagreement subsequently arises about whether the embryo should be deemed a juridical person, quasi-person, or non-person,⁵ we have not adequately addressed the significance of these three undisputed facts for regulating embryonic stem cell research.

On August 9, 2001, President Bush directed the Department of Health and Human Services (HHS) to approve limited federal funding for research on then sixty stem cell lines derived with the "informed consent" of parents who authorized the termination of their embryos.⁶ By informed consent, the Bush Administration meant "informed proxy consent" like the Clinton Administration before it.⁷ Yet, no court has ever found proxy consent adequate to justify ultra-hazardous, non-therapeutic research on

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incompetent living human subjects. Proxy consent to non-therapeutic research thwarts the underlying objectives of the informed consent doctrine applicable to human subject experimentation, including preserving autonomy, self-determination, liberty, and equality. Indeed, the very term "proxy informed consent" is doctrinally oxymoronic and must be recognized as a serious threat to all incompetent human subjects.

Strong legal and policy reasons exist to treat the living human embryo as something more than mere tissue, if not subject to the Federal Policy for the Protection of Human Subjects, including subpart A and subpart B,⁸ or to amended regulations providing greater protection than the fetal tissue research regulations, which the National Institutes of Health (NIH) prefers to invoke.⁹ A living human is more analogous to a "human subject" than human tissue. Categorizing the embryo as mere tissue does not recognize the special status of the human embryo, which a majority of Americans acknowledge,¹⁰ and instead renders the embryos vulnerable to the potential of ever-widening scientific manipulation in the years ahead. The embryo-as-tissue argument also forces the NIH to promulgate legal positions, such as its controversial Rabb Memorandum," ignoring Congress' clear intent to avoid harming living human embryos, and sweeping behind the public's veil of ignorance the possibility that human embryonic stem cells are totipotent-capable of generating every cell comprising a mature human person. If totipotent, human embryonic stem cells may not be substantially less deserving of protection than the human embryo.

We explore each of these ideas below without imposing our view that the human embryo is indeed a person and without discussing a mother's moral and legal entitlement to end the life of a living human in her womb.¹² Our point is that, regardless of your view about these important questions, living human embryos merit more protection than those who would gain financially and otherwise from manipulating them or simply donating them are inclined to acknowledge. If as a society we choose now to exclude altogether certain types of living human subjects from standard rules of medical ethics, the utilitarian fog into which medical researchers will travel in the years to come will surely take American medical researchers down the darkened and dead-ended roads previously traveled from Buchenwald¹⁸ to Tuskegee.¹⁴

I. DEVELOPMENTS IN THE IVF INDUSTRY AND STEM CELL RESEARCH HAVE OUTPACED POLICYMAKING

Today's controversy concerning federal funding for human embryonic stem cell research represents the confluence of three trends: the maturation of the in-vitro fertilization (IVF) industry with a protocol resulting in an exploding frozen human embryo population; the isolation of the human embryonic stem cell within the context of promising adult stem cell research; and policymaking that has not kept up with either. The IVF industry sprang into existence in England in 1978.¹⁵ During the last two decades, it has grown in the United States to 371 clinics nationally,¹⁶ with revenues that exceed an estimated \$350 million annually.¹⁷ The typical IVF clinic supervises the creation of many more living human embryos than are implanted because of the physical burden, medical risks, and costs associated with egg recovery.¹⁸

Clinics find it difficult to preserve and, once preserved, successfully fertilize oocytes.¹⁹ Accordingly, within a few hours of surgically removing oocytes, clinics fertilize the eggs and allow them to incubate.²⁰ Successful fertilization usually results in more embryos than women want to implant at one time.²¹ The remainder are cryo-preserved and remain frozen until the parents terminate, donate, or abandon them.²² As a result, one observer estimated in 1999 that 150,000 frozen human embryos were in storage with 19,000 added each year.²³ Anecdotal evidence suggests the number may be higher.

A radical, new purpose for embryo donation was foreshadowed in the early-1980s when mouse embryonic stem cells were derived for the first time from mouse blastocysts.²⁴ Soon thereafter, scientists discovered they were totipotent.²⁵ This finding "revolutionized mouse genetics."²⁶ Scientists set about trying to duplicate the success with humans. In November 1998, Professor James Thomson at the University of Wisconsin succeeded at isolating human stem cells.²⁷ This prompted President Clinton to ask the National Bioethics Advisory Commission (NBAC) to conduct a thorough review of the medical and ethical issues associated with human stem cell research.²⁸

Pursuant to the NBAC's recommendation, the NIH published its Draft Guidelines for Research Involving Human Pluripotent Stem Cells,²⁹ and on August 25, 2000, its final Guidelines (NIH Guidelines) allowing funding of research involving human embryonic stem cells if (1) the cells were derived without federal funds from frozen human embryos that were created for the purposes of fertility treatment; (2) the cells were "in excess of the clinical need" of the individuals seeking the treatment; (3) a clear separation existed between the decision to create the embryos for fertility treatment and the decision to donate them for research purposes; (4) no inducements were offered for the donation of the embryos; and (5) the informed consent of "individuals who have sought fertility treatment" was obtained.³⁰

The NIH was unable to award federal money to scientists under the NIH Guidelines because of litigation commenced on March 8, 2001,³¹ leading to entry of a stipulated stay pending the "outcome" of the Bush Administration's review of the NIH Guidelines.³² The legal controversy concerning embryonic stem cell research erupted into a vigorous political debate in the summer of 2001.³³ It was not muted until August 9, 2001, when President Bush decided his Administration's political solution to the debate.³⁴ His closely aligned legal response leading to dismissal of the legal action was announced on November 7, 2001.35 The Administration withdrew portions of the NIH Guidelines inconsistent with the President's decision to condition federally funded embryonic stem cell research on four criteria: (1) stem cells must have been derived from an embryo with the consent of the embryo's donors; (2) they may only have been derived from excess embryos created for reproductive purposes at fertility clinics; (3) the donor embryos must not have been donated in exchange for financial inducements; and (4) all embryonic lines must have been derived on or before August 9, 2001.³⁶

II. THE INFORMED CONSENT MODEL IS INCOMPATIBLE WITH EMBRYONIC RESEARCH

Both the Clinton Administration plan and Bush Administration plan for federally funding embryonic stem cell research require the informed consent of the living human embryo donor.³⁷ In essence, both plans view (1) informed consent as equivalent to proxy consent and (2) proxy consent as sufficient to immunize ultra-hazardous, non-therapeutic research on living humans. As stated earlier, no court has previously approved the latter proposition, and the former one is contradicted by the key medical ethical codes applicable to living human subjects.

A. The Doctrine of Informed Consent Bars Embryonic Stem Cell Research

The doctrine of informed consent applicable to human subject experimentation was essentially birthed by the Holocaust and subsequent Doctor's Trials resulting in the Nuremberg Code.³⁸ According to one commentator, American courts did not even accept the need for medical research on human subjects until 1935.³⁹ The Code prohibited altogether proxy consent for human experimentation.⁴⁰ The Code added that consent cannot immunize human subject experimentation unless the researcher complies with nine other requirements, including that no a priori reason exists to believe that death or disabling injury will occur, that the results of the experimentation are not procurable by other means, and that adequate preceding animal experimentation has taken place.⁴¹

The first systematic American effort to develop a doctrine of informed consent applicable to federally funded human subject experimentation incorporated the Code.⁴² The impact of the Code has since waned in some respects, yet it endures as the "most complete and authoritative statement of the law of informed consent to human experimentation."⁴³ The Code's influence on what some deem a replacement code of ethics,⁴⁴ the Declaration of Helsinki, has actually increased over time as a result of amendments. For example, the Declaration now expressly prohibits proxy consent to research if (1) the research is not necessary to promote the health of the population represented; (2) the research can be performed on legally competent individuals; and (3) the research is not based on sufficient animal studies.⁴⁵

Additionally, the Code remains "part of international common law and may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States."⁴⁶ Although federal courts have not found that the Code creates an implied right of action in circumstances where adequate alternative domestic remedies exist,⁴⁷ they have found, contrary to claims of qualified immunity, a "clearly established right" to bodily integrity in § 1983 litigation.⁴⁸ As the District of Massachusetts put it in *Heinrich v. Sweet*, "[A]t the very least, the judgment of the Nuremberg Tribunal regarding fundamental legal principles of human subject experimentation served as an explicit international declaration that the conduct alleged in this case 'shocked the conscience'....⁹¹⁹

Heinrich concerned 140 terminally ill patients under the care of the Massachusetts General Hospital and Brookhaven National Laboratory who were subjected to boron neutron radiation therapy without their knowledge or consent.⁵⁰ The study was deemed essential to evaluate the potential of radioactive medical treatment.⁵¹ *Heinrich* relied on another case where the University of Cincinnati College of Medicine and Cincinnati General Hospital subjected eighty-seven African-American cancer patients, who were terminal, indigent, and poorly educated, to massive doses of radiation to study its effects without their informed consent.⁵² Again, the scientific community considered the study critical to prepare for nuclear war, but the Southern District of Ohio volunteered that the complaint's allegations made out "an outrageous tale of government perfidy in dealing with some of its most vulnerable citizens."

Tragically, this tale has been duplicated with minor variations in the United States in a variety of cases involving non-therapeutic medical research on human subjects performed for valuable reasons.⁵⁴ The objectives of human embryonic stem cell research are also unimpeachable,

but the certain, immediate death that stem cell derivation poses for another living human subject—the human embryo—is in many respects as shocking as in these cases involving not proxy consent, but deception or inadequate informed consent by generally competent adults to nontherapeutic medical procedures with long-term medical consequences.

To understand the real impact of embryonic stem cell research on medical ethics, add to the certain, immediate death that derivation of stem cells causes human subjects the following additional violations of the Nuremberg Code and Declaration of Helsinki: (1) At most a handful of animal embryonic stem cell models exist revealing limited success at treating the diseases targeted by human embryonic stem cell research,⁵⁵ and (2) adult human stem cell research has the potential to achieve all of the objectives of embryonic stem cell research.⁵⁶ Thus, embryonic stem cell research is in direct violation of the two primary medical ethical codes governing experimentation on living human subjects.

B. Proxy Consent Has Never Been Held Sufficient to Immunize Ultra-Hazardous, Non-Therapeutic Research on Human Subjects

Proxy consent to ultra-hazardous, non-therapeutic human research, the additional conscious-raising concern not present in the cases explored above, has never been held effective as a matter of law in the United States. Two courts have approved minimally risky non-therapeutic kidney transplants from legally incompetent human subjects to relatives,⁵⁷ where the medical institutions involved obtained judicial consent, in addition to proxy consent, before proceeding, and the court appointed *guardian ad litems* to represent the incompetent human subjects.⁵⁸ Another court found that it was in the best interest of a forty-three year-old incompetent donor to undergo a bone marrow transplant involving "minimal risk" to the donor to save his brother's life.⁵⁹ In the last case, a court implied that a proxy could consent to her fifteen year old's decision to offer a skin graft to his cousin.⁶⁰

few The decisions involving more risky non-therapeutic experimentation on human subjects have disapproved of proxy consent.⁶¹ Two of these concerned studies on inmates,⁶² which if federally funded are now prohibited.⁶³ In one of these cases (not involving federal funding), the New York State Office of Mental Health (OMH) promulgated regulations with the strong support of the medical research community, which would have permitted the administration of experimental antipsychotic and psychotropic drugs, capable of "causing permanent harmful or even fatal side effects."⁶⁴ A New York appeals court held that the regulations violated the state and federal constitutional rights to due process and a common

law right to personal autonomy of the patients and residents under OMH care.⁶⁵ The Court explained:

The benefits of, and needs for, the medical research at issue are clear and evident; but at what cost in human pain and suffering to those subjects who are not capable of expressing either their consent or objection to participation?.... [H]owever laudable the ends which defendants seek to achieve may be, those results must be gained through means within their grant of authority and which properly safeguard the rights of the plaintiffs. It may very well be that for some categories of greater than minimal risk non-therapeutic experiments, devised to achieve a future benefit, there is at present no constitutionally acceptable protocol....⁶⁶

Maryland's highest court agreed in *Grimes v. Kennedy Krieger Inst.*, where researchers associated with Johns Hopkins University subjected otherwise healthy children to the probability of lead poisoning to assess the effect of various levels of lead dust abatement.⁶⁷ The Court found inadequate disclosure of these health risks to the children's parents,⁶⁸ and added: "[I]n our view, parents whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous non-therapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient."⁶⁹

The policy underlying the doctrine of informed consent to nontherapeutic research is to preserve the autonomy, self-determination, liberty, and equality of living human subjects, as well as to avoid fraud and abuse.⁷⁰ Proxy consent can never achieve these purposes. The justifying and legally immunizing role of consent depends upon the subject of the research herself agreeing to undergo a non-therapeutic procedure after deliberately weighing the fully disclosed risks. Consent offered by a proxy to non-therapeutic research for his incompetent ward, no matter how well informed, robs the patient of her autonomy and liberty and treats her as having lesser value. Viewed in this light, proxy informed consent is a sham and poor camouflage for mere utilitarianism:

Faced with a subject who presumably cannot consent, the Standard Model looks for someone else's consent. This is a big jump. After all, informed consent supposedly legitimates and justifies experimentation because that consent protects autonomy; but how can it when someone else is providing the consent? 'Proxy consent' is an oxymoron if consent truly aims at protecting self-autonomy and self-determination. Through proxy consent, the subject is labeled a morally impotent agent—less than autonomous. This is because the unspoken, but persistent, utilitarianism which underlies so much of our thinking about experimentation requires us to find some way to permit needed experiments while still giving lipservice to our values.⁷¹

Historically, informed consent has been deemed the most critical for vulnerable subjects such as the imprisoned, young, and elderly. It is crucial where the imbalance in the power relationship between the researcher and patient is severe,⁷² seriously divergent interests between the researcher and his or her subject may affect the scientist's judgment,⁷³ the researcher has more information about the consequences of the research for the subject,⁷⁴ and the subject places his or her profound trust in the investigator.⁷⁵ Human embryonic research is affected by all of these worst indicia of meaningless consent. The embryo donors seek to avoid the cost of preserving their embryos; researchers and Institutional Review Boards (IRBs) desire federal dollars, corporate sponsorship, and prestige; and the live human embryos themselves are, of course, incompetent and incapable of opposition.⁷⁶

Under these circumstances, we should be seriously concerned about authorizing medical research certain to kill incompetent living human subjects (not merely harm them as in *Grimes*) when the proposed benefits of the research may yet be obtained through harmless means and inadequate animal modeling justifies it. This type of medical research carried to its logical conclusion threatens harm to the elderly, handicapped, and mentally or physically ill.⁷⁷ It has never been vindicated in federal or state court, and it directly violates the Code and Declaration.⁷⁸ The *Grimes* court indicated that certainly no parent may consent to ultrahazardous, non-therapeutic research affecting her child, no researcher may consent to it because of the fiduciary-like relationship between the researcher and his subject,⁷⁹ and potentially no court may approve it.⁸⁰ Indeed, it is an open question as to whether even a competent person may consent to ultra-hazardous, non-therapeutic research on himself.⁸¹

III. THE LIVING HUMAN EMBRYO DEMANDS SPECIAL RESPECT

Some will vigorously object that *Grimes* is inapplicable to living human embryos, because embryos are not, after all, "children" in a legal sense.⁸² The embryo *in utero* is not a "person" within the meaning of the Fourteenth Amendment,⁸³ rendering any direct analogy to the children in *Grimes* inappropriate. Notwithstanding this, even strong pro-abortion proponents acknowledge that *Roe v. Wade*⁸⁴ has no necessary bearing upon the *ex utero* living human embryo where maternal and fetal rights are not in opposition.⁸⁵ Professor John Robertson, for example, concedes that efforts to limit the number of cyropreserved embryos,⁸⁶ regulate destruction of human embryos,⁸⁷ require their donation,⁸⁸ and restrict or ban non-therapeutic research on living human embryos⁸⁹ are constitutional.

Robertson adds, "[O]ne may reject the right-to-life position that early embryos are themselves persons...and still agree that early embryos deserve 'special respect'....⁹⁹⁰ He acknowledges "wide consensus" favoring this view, which he contends does not hinge on religious convictions, but instead on the essential nature of the embryo as a living, genetically unique human with the potential to develop into a person.⁹¹ Courts echoing this theme include Kass v. Kass⁹² and Davis v. Davis,⁹³ which expressly rejected the findings of the trial court that the embryo is a person,⁹⁴ and of the appellate court that it was mere property "no different from any other human tissue.⁹⁵ Instead, the Davis court held that living human embryos "occupy an interim category that entitles them to special respect because of their potential for human life.⁹⁹⁶

The NBAC and the NIH agreed that the embryo deserves special respect, but without influencing the choice of regulatory frameworks they believe applicable to it. In the final analysis, they and Robertson interpret "special respect" for the living human embryo to mean little more than that researchers may not create embryos solely for research purposes.⁹⁷ The "informed consent" rules they believe applicable to living human embryos are the same ones applicable to fetal tissue transplantation research,⁹⁸ as if the doctrine of informed consent ever applied to inanimate tissue. A more intellectually honest description of this form of consent is merely "full disclosure," since no living human subject is involved. Tissue cannot generate anything beyond itself, whereas the human embryo is totipotent.⁹⁹ Accordingly, the fetal tissue research guidelines appear to have no relevance to living human embryos and, even if applicable, are not truly rules of informed consent.¹⁰⁰

Embryonic stem cells are more like tissue than living human embryos, but still not enough to complete the analogy.¹⁰¹ The NIH concedes that human embryonic stem cells "can form virtually every type of cell found in the human body."¹⁰² Nevertheless, the NIH has insisted that the cells are merely pluripotent, because embryonic stem cells "are unable to give rise to the placenta and supporting tissues necessary for development in the human uterus."¹⁰³ The placenta and the supporting tissues come from trophoblast cells.¹⁰⁴ Thus, in scientific terms, the NIH's claim is that human embryonic stem cells can form all cell types, except trophoblast cells. The scientific record refutes this. In fact, the same scientific study that the NIH cites to demonstrate the alleged potential for human embryonic stem cell

research,¹⁰⁵ states that human embryonic stem cells can form trophoblast cells.¹⁰⁶

In addition, NIH Director Harold Varmus has conceded that the NIH has never performed the necessary experiments to rule-out the possibility that human embryonic stem cells when implanted in a woman may congregate and give rise to a born person.¹⁰⁷ Animal studies using embryonic stem cells suggest this is likely.¹⁰⁸ Accordingly, some stem cell researchers are sharing their misgivings about not admitting this to the public.¹⁰⁹ By contrast, there is no chance tissue can give rise to a born person. Therefore, embryonic stem cells deserve more protection than mere fetal tissue regulations offer.

IV. EXISTING FEDERAL AND STATE LAWS WOULD PROHIBIT FEDERALLY FUNDING ULTRA-HAZARDOUS, NON-THERAPEUTIC RESEARCH ON LIVING HUMAN EMBRYOS

Existing federal and state law potentially or actually applicable to living human embryos provide additional reason to believe that specially respecting them requires more protection than the NIH and others acknowledge. Subparts A and B of the Federal Human Subjects Policy may be interpreted to ban embryonic stem cell research altogether, and the Dickey Amendment may be interpreted to ban research on living human embryos. State laws affecting living human embryos establish tort liability for damages to the unborn and restrict or ban research on embryos and authorize their adoption. We explore these rules below.

A. If Applicable, Federal Human Subjects Policy, Subparts A and B, Prohibit Federally Funding Human Embryonic Stem Cell Research

The springboard for Grimes' finding that researchers owe quasifiduciary obligations to human subjects was, in addition to the Nuremberg Code, the Federal Policy for the Protection of Human Subjects, including Subpart A and Subpart B (Human Subjects Policy).¹¹⁰ Subpart A states it is applicable "to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department...."¹¹¹ Human are defined as "living individual[s] about whom subjects an investigator...conducting research obtains (1) data through intervention individual, or (2) identifiable interaction with the or private information."¹¹² This definition does not reference a legal juridical person.

Under Subpart A, the informed consent requirement states: "[N]o investigator may involve a *human being* as a subject in research covered by this policy unless the investigator has obtained the *legally effective* informed

consent of the subject or the subject's legally authorized representative."¹¹³ The rule does not make clear whether, by "human being," someone or something other than a "human subject" was intended; however, it defines as an element of necessary consent, "a statement that the particular treatment or procedure may involve risks to the subject (or to the *embryo* or fetus, if the subject is or may become pregnant) which are currently unforeseeable."¹¹⁴

Accordingly, Subpart A does not state that its application is limited to living human persons and leaves open the possibility that a living human embryo is a "human being," which may be equivalent to a "human subject" and, therefore, regulated. A leading definition of human subject experimentation outside of the federal regulatory framework supports this view: Human subject experimentation is "any manipulation, observation, or other study of a human being—or of anything related to that human being that might subsequently result in manipulation of that human being done with the intent of developing new knowledge and which differs in any form from customary medical (or other professional practice)."¹¹⁵ The counterargument is that an "individual" frequently is a natural person, and the "human being" referenced in Subpart A's rules of informed consent may not be more expansive than its definition of "human subject." In rebuttal, the NIH itself has implied that human embryos are individuals.¹¹⁶

The informed consent rule of Subpart A implies that some proxy consent may not be legally effective, a fact the *Grimes* court emphasized in calling for prior judicial (not mere IRB) review before implementing non-therapeutic research on a human subject.¹¹⁷ The court opined, "[s]cience cannot be permitted to be the sole judge of the appropriateness of such research methods on human subjects....,"¹¹⁸ Likewise, in the single other reported instance of non-therapeutic experimentation posing a greater than minimal risk to the living human subject, a New York appeals court found that proxy consent would be ineffective under state law.¹¹⁹

Subpart B of the Human Subjects Policy, considered by some more relevant to human embryonic research than Subpart A,¹²⁰ "applies to all research involving pregnant women or human fetuses, and to *all research involving the in vitro fertilization of human ova*, conducted or supported by" HHS.¹²¹ The definition of IVF is "any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means."¹²² Subpart B incorporates all of Subpart A's obligations and calls for additional IRB duties.¹²³ The NIH and others resist an interpretation of IVF within the meaning of Subpart B incorporating extra-corporeal embryo research.¹²⁴ The NIH believes the embryo is only protected under the Human Subjects Policy if it is *in utero.*¹²⁵ Regardless, it is clear that the human embryo, which is the subject of the Clinton and Bush plans for stem cell research, may only come from IVF, and that Subpart B applies to "all research involving...in vitro fertilization."¹²⁶

If the Human Subjects Policy is thus applicable to human embryos, we must decide whether proxies can provide legally effective consent to ultrahazardous, non-therapeutic derivation of stem cells from living human embryos. In addition, we must evaluate whether this derivation is necessarily related to research utilizing those stem cells. Subpart A (which is incorporated in Subpart B) requires that IRBs ensure that risks to human subjects are minimized and reasonable in relation to anticipated benefits.¹²⁷

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research may not be "greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."¹²⁸ In addition, IRBs must incorporate additional safeguards for subjects vulnerable to coercion.¹²⁹ Thus, to the extent derivation of stem cells is inherently related to their use, Subpart A would prevent federally funding embryonic stem cell research.

B. The Dickey Amendment Protects the Living Human Embryo From Any Federally Funded Procedure Posing More Than Minimal Risk to It

Concededly, it may be argued that the Human Subjects Policy does not regulate research on living human embryos. The so-called Dickey Amendment defines "human embryo" as "any organism, not protected as a human subject under the Human Subjects Policy as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."¹³⁰ Accordingly, the NIH believes that we must derive our hermeneutic of special respect for the human embryo from memorandum issued on January 15, 1999, by HHS General Counsel interpreting Harriet S. the Dickey Amendment Rabb, (Rabb memorandum).131

The Dickey Amendment, included in every HHS appropriations bill since 1995,¹³² states: "None of the funds made available by this Act may be used for...research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*....^{*133} Interpreting this language, the Rabb memorandum claimed that the Dickey Amendment bans federal funding of the derivation of embryonic stem cells—a

euphemism for the procedure that kills the living human embryo—but not research utilizing the derived embryonic stem cells.¹³⁴

This interpretation flatly contradicted legislative history through 2001, and the original purpose for passing the Dickey Amendment—to prevent embryonic research.¹³⁶ Until 1994, a *de facto* federal ban on human embryo research existed.¹³⁶ The Clinton Administration took steps to reverse this ban pursuant to the recommendation of an *ad hoc* advisory committee, the Human Embryo Research Panel (HERP),¹³⁷ while still prohibiting the creation of embryos for research purposes.¹³⁸ In testimony before the House Appropriations Committee, NIH Director Varmus stated that he "firmly agree[d]" with several portions of the HERP report, and told the Committee that the NIH was currently deciding whether to go forward with funding.¹³⁹

Before the NIH could approve any grants, Congress passed the Dickey Amendment for the first time.¹⁴⁰ Opponents of the amendment objected to it on the grounds that it would foreclose action on the HERP report and "segregate [human embryo] research into private laboratories, which are not subject to any set scientific or ethical guidelines."¹⁴¹ Senator Boxer agreed that the Dickey Amendment amounted to "a *total prohibition* of Federal funding for human embryo research."¹⁴² That first year, the House Appropriations Committee rejected an alternative rider offered by Representative John Porter, which would have codified President Clinton's directive by prohibiting only the funding of the *creation* of embryos for research purposes.¹⁴³

During the 1997 reauthorization cycle, the full House roundly rejected an amendment offered by Representative Lowey and identical to the Porter Amendment.¹⁴⁴ Again, the proponents and opponents of embryo research operated on the same premise (i.e., that the Dickey Amendment banned federal funding of *all* research dependent upon the destruction of an embryo).¹⁴⁵ Porter argued, for example, that repeal of the Dickey Amendment was necessary because federal funding of research "could also lead to breakthroughs *in the use of embryonic stem cells.*"¹⁴⁶ No further attempts were made to modify the Dickey Amendment until the 2001 reauthorization cycle. Therefore, the conclusion is inescapable that the Rabb memorandum, NIH Guidelines, and even the proposed Bush plan proposing funding on sixty stem cell lines necessarily derived through the termination of human embryos were inconsistent with the Dickey Amendment as passed from 1995 to 2000.¹⁴⁷

In 2001, the Senate was widely expected to modify the Dickey Amendment; however, the national tragedy of September 11 changed the political landscape. The House reauthorized the Amendment without change, but interpreted its action as consistent with the proposed Bush plan.¹⁴⁸ Representative McDermott and Senator Arlen Specter proposed amendments permitting liberal embryonic stem cell research.¹⁴⁹ Both failed. The resulting Amendment is not a vindication of the Rabb memorandum's derivation-versus-use dichotomy.¹⁵⁰ Nor is it a vindication of the limited protection that President Clinton; Representatives Lowey, Porter, and McDermott; and Senator Specter offered (i.e., prohibiting the funding merely of the *creation* of embryos for research purposes).

Rather, the resulting Amendment is a vindication of the principles permitting research on already dead fetuses. President Bush refused to justify research on living human embryos based on the derivation-versususe dichotomy; he authorized research only on embryos terminated before August 9, 2001, without creating federal incentives to kill more.¹⁵¹ Accordingly, the "special respect" Congress and the President wish to accord living human embryos is best understood as security from any procedure that would pose more than minimal risk to them, including useinspired derivation of stem cells.

C. State Regulations Affecting Living Human Embryos Limit or Ban Embryonic Research, Permit Adoption, and Create Tort Liability

Likewise, the special respect that state law affords living human embryos resembles more closely human subjects than dead fetuses or human tissue. Thirty-seven states and the District of Columbia have recognized expressly or implicitly by statute, resolution, and/or court decision that "fertilization" and "conception" initiates the life of a human being.¹⁵² In many of these states, courts impose tort liability for damages to the unborn without regard (for purposes of standing) to the viability of the child at the time of injury.¹⁵³ Ten states expressly regulate human embryonic research; seven of these states permit only therapeutic human embryonic research, ¹⁵⁴ Three additional states tried to regulate human embryonic research, but their regulations were overbroad.¹⁵⁵ Two states have enacted a rudimentary legal framework for human embryo adoption,¹⁵⁶ a concept ordinarily not applied to mere tissue or dead human subjects.

V. A PERMANENT LEGAL COMPROMISE NO WEAKER THAN THE BUSH PROPOSAL IS URGENTLY NEEDED

In the final analysis, the nascent federal and state legal regime applicable to human embryos reflects the objective reality that they are living members of the human species, not merely inanimate tissue. Although not yet judicially recognized as persons within the meaning of the Fourteenth Amendment, the legal regime treats them as juridical quasi-persons with some of the rights of incompetent living persons. A permanent legal compromise is necessary to protect these quasi-persons against ever-widening scientific manipulation threatened by proponents of broader federal funding for embryonic stem cell research and to prevent further erosion of the standard human subject experimentation rules.¹⁵⁷

We would have preferred to prevent any embryonic stem cell research.¹⁵⁸ The policies informing the case law and legislative intent explored above, that we believe strongly militate in favor of rendering standard human subject experimentation rules applicable to embryos, include (1) all other living humans-even the least desirable criminalsare specially protected; (2) treating any living human as expendable impacts all by lowering the ethical bar; (3) derivation of stem cells is immediately terminal for the embryo and unlikely to have any therapeutic impact on embryos as a class in the near future; (4) proxy consent can never achieve the objects of informed consent, including autonomy, selfdetermination, liberty, and equality; (5) those urging, monitoring, and even offering proxy consent for derivation of stem cells have much to gain from it; and (6) scientists have not satisfied their burden of proving that (a) embryonic stem cell research is likely to prove successful; (b) its speculative objectives cannot be secured through other means; and (c) embryonic stem cells are merely pluripotent.

If embryonic stem cells are merely pluripotent, stem cell lines extracted without the legally effective informed consent of their donors would still be illegal.¹⁵⁹ If totipotent, embryonic stem cells may also be subject to the Dickey Amendment, because they qualify as "human embryos" within the meaning of the Amendment as interpreted by the NIH. That is, the Dickey Amendment defines "human embryo" as "any organism...that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."¹⁶⁰ Although the Amendment does not define "organism," the NIH contends that it means "an individual constituted to carry out all life functions."¹⁶¹ By definition, a totipotent cell is capable of developing into a mature individual if nurtured in the right environment and, thus, able to carry out all life functions.¹⁶² Under these circumstances, the Dickey Amendment would prohibit research posing more than minimal risk to embryonic stem cells-a fact Congress has so far not considered probably because the NIH has swept under the rug the potential totipotency of human embryonic stem cells.

Nevertheless, the advantage of permanently legislating the proposed

Bush plan over the Clinton plan is that the former offers a meaningful interim category between the embryo-as-tissue and embryo-as-person regulatory framework. The idea of federally funding research on a limited number of already terminated human embryos while permitting states to ban it altogether, puts some flesh on the special respect most Americans believe is due the living human embryo. Space prevents us from expounding on a proposed Subpart E (Additional Protections for Human Embryos), and the additional legislation we believe necessary to accord meaningful special respect to the living human embryo. Suffice it to say that we believe the Human Subjects Policy must carefully distinguish the various forms of consent and disclosure, removing any possibility that proxies may give their consent to ultra-hazardous, non-therapeutic research on living humans, except as permitted in our proposed revised permanent Dickey Amendment.¹⁶³ Furthermore, Subpart E should generally permit research posing no more than a minimal risk to living human embryos. Finally, federal or state laws should ban creation of human embryos for research purposes,¹⁶⁴ ban cloning,¹⁶⁵ limit the number of human embryos that may be cyropreserved in the IVF treatment process,¹⁶⁶ regulate the disposition of living and frozen human embryos,¹⁶⁷ and encourage embryo adoption over donation.¹⁶⁸ In this manner, we can ensure special respect for the living human embryo.

References

1. Robert George, Stem Cell Research: A Debate; Don't Destroy Human Life, WALL ST. J., July 30, 2001, at A18. Robert P. George, J.D., D. Phil. is the McCormick Professor of Jurisprudence, Princeton University, and Director of the James Madison Program in American Ideals and Institutions. On 2002. January 18. President Bush appointed Dr. George to be one of eighteen members of the President's Council on Bioethics charged with keeping apprised the President of new developments in the bioethics arena and providing a forum for discussion and evaluation of those issues.

2. John A. Robertson, Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction, 59 S. CAL. L. REV. 939, 974-75 (1986) [hereinafter Robertson I]; John A. Robertson, In the Beginning: The Legal Status of Early Embryos, 76 VA. L. REV. 437, 437, 444 & n.24, 445, 515 (1990) [hereinafter Robertson II].

3. *Id.*

4. See, e.g., Gabriel S. Gross, Comment, Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis, WIS. L. REV. 2000, at 855, 856.

5. See Davis v. Davis, No. E-14496, 1989 WL 140495, at *1 (Tenn. Cir. Ct. Sept. 21, 1989) (embryos are children in vitro), rev'd, No. 180, 1990 WL 130807 (Tenn. Ct. App. Sept. 13, 1990) (embryos are property), aff'd, 842 S.W.2d 588 (Tenn. 1992) (embryos deserve "special respect" as neither property nor person), cert. denied, 507 U.S. 911 (1993).

6. Press Release, Office of the Press Secretary, White House, President's Embryonic Stem Cell Research Policy (Aug. 9, 2001) [hereinafter Bush Press Release] (on file with author), *available at* www.whitehouse.gov/news/releases/2001.

7. Compare George W. Bush, Stem Cell Science and the Preservation of Life, N.Y. TIMES, Aug. 12, 2001, at 13, with National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,980 (Aug. 25, 2000) [hereinafter NIH Guidelines].

8. See 45 C.F.R. § 46 (2000).

9. See NIH Guidelines, supra note 7 (citing 42 U.S.C. § 289g-1).

10. Robertson II, supra note 2, at 515.

11. See infra note 131 and accompanying text.

12. See Robertson II, supra note 2, at 499 ("The constitutionality of state laws that seek to prevent the discard or destruction of IVF embryos does not depend on whether Roe v. Wade is reversed."); Christine L. Feiler, Note, Human Embryo Experimentation: Regulation and Relative Rights, 66 FORDHAM L. REV. 2435, 2446 (1998)("Experimentation involving deliberately fertilized embryos...is fundamentally different from both the abortion and IVF scenarios because individual reproductive autonomy is not implicated."); Sharon M. Parker, Note, Bringing the "Gospel of Life" to American Jurisprudence: A Religious, Ethical andPhilosophical Critique of Federal Funding for Embryonic Stem Cell Research, 17 J. CONTEMP. HEALTH L. & POL'Y 771, 772 (2001) ("[T]he Supreme Court's abortion jurisprudence has not been dispositive of the issues surrounding early human life.").

13. German scientists deliberately infected patients with typhus to study the rapidity of the disease at Buchenwald concentration camp during World War II.

14. So that researchers could study the

terminal stages of syphilis, African Americans suffering from the disease were not told about or given potential remedies. See William J. Curran, The Tuskegee Syphilis Study, 289 NEW ENG. J. MED. 730 (1973).

15. Victor Cohn, First U.S. Test-Tube Baby is Born; Norfolk Test-Tube Baby First in United States, WASH. POST, Dec. 29, 1981, at A1.

16. The Centers for Disease Control and Prevention (CDC) reported that the number of IVF clinics in 1998 was 360. CTR. FOR DISEASE CONTROL & PREVENTION, 1998 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 4 (2000) [hereinafter CDC REPORT]. However, the Society for Assisted Reproductive Technology reports that the number of IVF clinics in 2001 is 371 (on file with author).

17. Judith F. Daar, Regulating Reproductive Technologies: Panacea or Paper Tiger, 34 HOUS. L. REV. 609, 613-14 (1997).

18. J.B. v. M.B., 783 A.2d 707 (N.J. 2001).

19. Id.

20. Id; Warren A. Kaplan, Note, Fetal Research Statutes, Procreative Rights, and the 'New Biology': Living in the Interstices of the Law, 21 SUFFOLK U. L. REV. 723, 727-28 (1987).

21. J.B., 783 A.2d at 707; Opportunities and Advancements in Stem Cell Research: Hearing Before the Gov't Reform Subcomm. on Criminal Justice, Drug Pol'y, & Human Res., 107th Cong. n.16 (2001) [hereinafter Opportunities and Advancements Hearing] (statement of JoAnn L. Davidson, Director, Snowflakes Embryo Adoption Program). IVF clinics implant only about three embryos per IVF cycle. J.B., 783 A.2d at 707; Kaplan, supra note 20, at 730. According to calculations based on CDC data, the average cycles of IVF treatment necessary for a live birth for women under thirty-five is 3.1; 3.8 for women between 35-37; 5.6 for women between 38-40; and 12.2 for women over forty (on file with author).

22. The typical contract between an IVF clinic and its patients provides that the clinic will store patients' frozen embryos for a fixed period of time, usually not more than five years. Then, the clinic offers genetic parents the option of extending storage for a fee varying between \$100 and \$500 annually, implanting the embryos, terminating them, or donating them for some purpose. *Opportunities and Advancement Hearing, supra* note 21, at n.12 and accompanying text.

23. Lori B. Andrews, Embryonic Confusion; When You Think Conception, You Don't Think Product Liability; Think Again, WASH. POST, May 2, 1999, at B1. No law requires that genetic parents be informed about all their options, and many genetic parents report they were never advised, for example, that they could place their unwanted human embryos for adoption and implantation by adoptive parents.

24. David Solter, Cloning and Embryonic Stem Cells: A New Era in Human Biology and Medicine, 40 CROAT. MED. J. 3 (1999).

26. Id.

27. Gross, *supra* note 4, at 866-67. At roughly the same time, an independent investigation team lead by John Gearhart at Johns Hopkins University derived stem cells from cadaveric fetal tissue. *Id.* at 866 n.70.

28. Id. at 866-67 (referencing the NBAC's report, Ethical Issues in Human Stem Cell Research).

29. See Draft National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (Dec. 2, 1999).

30. NIH Guidelines, *supra* note 7.

^{25.} Id.

31. Nightlight Christian Adoptions v. Thompson, Civil Action No. 1.01CV00502-RCL (D.D.C. Mar. 8, 2001).

32. Nightlight Christian Adoptions v. Tommy G. Thompson, Civil Action No. 1.01CV00502-RCL (D.D.C. May 7, 2001) (order granting stipulated stay), *available at* http://www.nihsuit.com. During the pending of the Bush Administration review and for thirty days thereafter, HHS was ordered to continue its "present policy of not funding any research involving use of pluripotent stem cells derived from human embryos." *Id.*

33. See, e.g., Opportunities and Advancements Hearing, supra note 21; Stem Cell Research: Hearing Before the Subcomm. on Labor, Health & Human Servs., & Educ., 107th Cong. (2001) [hereinafter Stem Cell Hearing].

34. Bush Press Release, supra note 6.

35. Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells (Nov. 7. 2001). at http://grants.nih.gov/grants/guide/notic e-files/NOT-OD-01-003.html; Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells Establishment of NIH Human and Embryonic Stem Cell Registry (Nov. 7, 2001), http://grants.nih.gov/ at grants/guide/notice-files/NOT-OD-02-005.html; Memorandum from Alex M. Azar, General Counsel, Dep't Health & Human Serv., to Ruth Kirchstein, Acting Dir., Nat'l Inst. Health (Jan. 11, 2002) (on [hereinafter file with author) Azar memorandum].

36. See Bush, supra note 7; Bush Press Release, supra note 6.

37. The NIH Guidelines require that the informed consent include "a statement that the embryos will be used to derive human pluripotent stem cells for research" from the "individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes." NIH Guidelines, *supra* note 7. Likewise, the Bush plan requires a statement that each cell line was derived from an embryo with the consent of the embryo's donor. *See supra* note 36 and accompanying text.

38. See United States v. Carl Brandt, II TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (1946-49).

39. Karine Morin, The Standard of Disclosure in Human Subject Experimentation, 19 J. LEGAL MED. 157, 169 (1998) (citing Fortner v. Koch, 261 N.W.2d 762 (1935) ("We recognize the fact that if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him and must not vary too radically from the accepted method of procedure.")). Only one case preceding the Nuremberg Code dealt with non-therapeutic human subject experimentation and held that a fifteenyear-old minor, together with his parent, could consent to a non-therapeutic skin graft benefiting the minor's cousin. George J. Annas, Mengele's Birthmark: The Nuremberg Code in United States Courts, 7 J. CONTEMP. HEALTH L. & POL'Y 17 (1991) (citing Bonner v. Moran, 126 F.2d 121, 121 (D.C. Cir. 1941)).

40. The Nuremberg Code states, "[t]he voluntary consent of the human subject is absolutely essential," and the human subject "should have legal capacity to give consent; should be so situated as to be able

to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." United States v. Carl Brandt, II TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10, at 181-82 (1946-49).

41. Id. See also Annas, supra note 39, at 21.

42. The original guidelines applicable to human subject medical experimentation adopted by the NIH and the Department of Defense incorporated the Nuremberg Code. NAT'L INST. HEALTH, HANDBOOK ON THE UTILIZATION OF NORMAL VOLUNTEERS IN THE CLINICAL CENTER § 3.06 (1961); Memorandum for the Secretary of the Army, Navy, Air Force (Feb. 26, 1953) (cited in In re Cincinnati Radiation Litig., 874 F. Supp. 796, 821 (S.D. Ohio 1995)). See also Morin, supra note 39, at 169 ("By 1952, the Armed Forces Medical Policy Council adopted a resolution whereby principles found in the Nuremberg Code were to become the guidelines of research related to atomic, biologic, and chemical warfare.").

43. GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 21 (1977).

44. Id. at 24 (stating that the medical community adopted the Declaration out of a sense that the Code was a context-bound relic of Nazi Germany too inflexible and rooted in natural law for modern medicine); Richard Garnett, Why Informed Consent? Human Experimentation and the Ethics of Autonomy, 36 CATH. LAW. 455 (1996).

45. Initially, the Declaration of Helsinki expressly allowed proxy consent "in accordance with national legislation" for therapeutic human experimentation, but not necessarily non-therapeutic experimentation. Declaration of Helsinki (1964), http://www.cirp.org/library/ethics Declaration /helsinki. The otherwise preserved Code's the emphasis on informed, uncoerced, and competent consent and, regardless of consent, left the responsibility for the human subject on the researcher. The Declaration also firmly stated, "Concern for the interests of the subject must always prevail over the interests of science and society." Id. The Declaration has been amended five times since, including as recently as October 2000, so that now proxy consent for legally incompetent persons is expressly prohibited unless "the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons." Declaration of Helsinki (2000), http://www.wma.net/e/policy/17-c_e.html. The amended Declaration adds that vulnerable research populations merit special protection and that human experimentation should not proceed until there is "adequate laboratory and, where appropriate, animal experimentation." Id.

46. ANNAS ET AL., *supra* note 43, at 21. *Accord* Heinrich v. Sweet, 49 F. Supp. 2d 27, 42 (D. Mass. 1999) (citing *In re* Cincinnati Radiation Litig., 874 F. Supp. 796, 821 (S.D. Ohio 1995)).

47. *Heinrich*, 49 F. Supp. 2d at 42 (citing White v. Paulsen, 997 F. Supp. 1380, 1383-84 (E.D. Wash. 1998)).

48. Heinrich v. Sweet, 62 F. Supp. 2d 282, 319-21 (D. Mass. 1999) (referencing 42 U.S.C. § 1983 (2001) and citing *In re* Cincinnati Radiation Litig., 874 F. Supp. at 821). These courts also considered tort law relating to informed consent and the progeny of *Griswold v. Connecticut*, 381 U.S. 479 (1965) and *Eisenstadt v. Baird*, 405 U.S. 438 (1972). See Heinrich, 62 F. Supp. 2d at 320; *In re* Cincinnati Radiation Litig., 874 F. Supp. at 816-19.

49. Heinrich, 62 F. Supp. 2d at 321.

- 50. Id. at 290.
- 51. Id. at 294.

52. In re Cincinnati Radiation Litig., 874 F. Supp. at 800-01, 803. Researchers hoped to develop a baseline for determining how much radiation exposure was too much and how shielding could decrease its deleterious effects.

53. Id. at 800.

54. See United States v. Stanley, 483 U.S. 669 (1987) (discussing the secret administration of LSD to soldiers by the CIA and the Army in the 1950s and 1960s); CIA v. Sims, 471 U.S. 159 (1985); Jaffee v. United States, 663 F.2d 1226 (3d Cir. 1981), cert. denied, 456 U.S. 972 (1982) (discussing the intentional exposure of soldiers to radiation in the 1950s); Whitlock v. Duke Univ., 637 F. Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987) (discussing a diver who suffered organic brain damage from decompression experiments after defective informed consent); Begay v. United States, 591 F. Supp. 991 (1984), aff'd, 768 F.2d 1059 (9th Cir. 1985) (discussing tests involving the exposure of Navajo miners to radiation); Zeleznik v. Jewish Chronic Disease Hosp., 366 N.Y.S.2d 163 (1975) (discussing chronically ill and debilitated patients who were injected with cancer cells without their consent); Application of Hyman, 248 N.Y.S.2d 245 (1964), rev'd, Hyman v. Jewish Chronic Disease Hospital, 251 N.Y.S.2d 818 (1964), rev'd, 258 N.Y.S.2d 397 (1965)

(discussing chronically ill, incompetent non-cancer patients injected with foreign cancer cells without their informed consent because "the doctors did not wish to stir up any unnecessary anxieties in the patients," Hyman, 251 N.Y.S.2d at 820); W.J. Curran, The Tuskegee Syphilis Study, 289 NEW ENG. [. MED. 730 (1973) (discussing that African Americans infected with syphilis were not informed of the availability of penicillin for treatment of the illness, so that scientists could examine the effects of their illness); Franz J. Ingelfinger, Ethics of Experiments on Children, 288 NEW ENG. J. MED. 791 (1973) (discussing the Willowbrook studies, where mentally ill children were deliberately infected with hepatitis); Jeffrey H. Barker, Human Experimentation and the Double Facelessness of a Merciless Epoch, 25 N.Y.U. REV. L. & SOC. CHANGE 603 (1999) (discussing a patient with ornithine transcarbamylase deficiency disease subjected to non-therapeutic genetic experimentation with defective informed consent).

55. Three mice studies examining the impact of embryonic stem cells on diabetes exist, none of which produced results nearly as good as adult stem cell models. See Opportunities and Advancements Hearing, supra note 21 (supplemental statement of David Prentice, Professor of Life Sciences, Indiana State University). The authors are aware of no other published reports of successful treatment of animal models of disease. Proponents of embryonic stem cell research were repeatedly asked to provide additional examples of successful animal studies in Congressional hearings. Dr. Gerald Fischbach responded by implying that the dopaminergic neurons generated from mouse embryonic stem cells in a study performed by Dr. Ronald McKay at the NIH led to improvements in the condition

of rats. Id. (statement of Dr. Gerald Fischbach, Director, National Institute of Neurological Diseases and Stroke). However, Fischbach misstated the extent of McKay's study, which did not involve actually implanting the embryonic stem cells in Parkinson's rats. Rather, McKay called for additional "studies in Parkinsonian rodents...to further assess the function and safety of [embryonic stem] cell-derived DA neurons in vivo." Id. (supplemental of David statement Prentice). If in the future a few additional authentic animal studies predating President Bush's decision to federally fund embryonic stem cell research are uncovered, the extent of animal modeling using embryonic stem cells will still have been totally inadequate to satisfy the Code and Declaration.

56. Opponents have been forced to concede that adult stem cell research, although new, is proving remarkably successful. For example, adult stem cell research has been used to treat various forms of cancer, autoimmune diseases, immunodeficiencies and anemias, stroke, cartilage and bone diseases, blood and liver disease, cornea failure, and cardiac damage. See Opportunities and Adancements Hearing, supra note 21, at nn.49-66 and accompanying text (statement of David Prentice); Id. at nn. 5-6 and accompanying text (supplemental statement of David Prentice). Nevertheless, opponents assert that embryonic stem cell research remains critical, because adult stem cells allegedly are hard to isolate, have not been isolated from all tissues of the body, may be difficult to grow, are not pluripotent, and may contain more genetic abnormalities than embryonic stem cells. DEP'T HEALTH & HUMAN SERVS., HUMAN PLURIPOTENT STEM CELL RESEARCH GUIDELINES (2001); NAT'L

INST. HEALTH, STEM CELLS: A PRIMER (2000) [hereinafter PRIMER]. Substantial evidence contradicts each of these claims. See, e.g., Opportunities and Advancements Hearing, supra note 21. (statement and supplemental statement of David Prentice) (summarizing the literature).

57. See Hart v. Brown, 289 A.2d 386 (1972) (approving the transplant of a kidney from one seven-year-old twin to another where the donor was expected to live a normal and productive life afterwards and the recipient twin had only a 50% chance of surviving for five years without the kidney); Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969) (approving the donation by a mentally incompetent adult of her kidney to her twenty-eight-year-old brother).

58. Hart, 289 A.2d at 374. Notably, most statutory state schemes permitting surrogate decision-making in various health care treatment situations contain provisions for notice to the individual patient and/or exhaustive administrative and judicial review procedures. See, e.g., T.D. v. New York State Office of Mental Health, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996) (making this point with regard to New York state surrogacy regulations).

59. Matter of Doe, 481 N.Y.S.2d 932 (N.Y. App. Div. 1984) (per curiam).

60. Bonner v. Moran, 126 F.2d 121 (App. D.C. 1941) (finding that guardian (aunt) consent was necessary for a fifteenyear-old to give a skin graft to a badly burned cousin; appellate court did not state that parental consent was sufficient for non-therapeutic research).

61. See Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001); T.D. v. New York State Office of Mental Health, 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995), aff'd, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996) (finding that a state agency could not authorize non-therapeutic experiments on mental patients including both adult and minor subjects).

62. T.D., 650 N.Y.S.2d at 176; Kaimowitz v. Michigan Dep't of Mental Health, Civil No. 73-19434-AW (Cir. Ct. Wayne County, Mich. July 10, 1973).

63. See Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, Subpart C.

64. T.D., 626 N.Y.S.2d at 177-78, 184 (noting that the medical community supports research guidelines and that research is not federally funded).

65. Id. at 176.

66. Id. at 177.

67. Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001).

68. Id.

69. Id.

70. See Richard Delgado & Helen Leskovac, Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice, 34 U.C.L.A. L. REV. 67, 78, 124-25 (1986); Garnett, supra note 44, at 457; Morin, supra note 39, at 165, 177, 210 (citing Robert Levine, The Nature and Definition of Informed Consent in Various Research Settings, in NATIONAL COMMISSION FOR Тне PROTECTION OF Human SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH. THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter BELMONT REPORT]).

71. Garnett, supra note 44, at 486.

72. Id. at 477-81 (citing 45 C.F.R. §§ 46.304-.305; 306(a)(2)(i-iii) (1994) (limiting the scope of prisoner research eligible for federal funding, notwithstanding that prisons are ideal places for behavioral research); Kaimowitz v. Michigan Dep't of Mental Health, Civil No. 73-19434-AW (Cir. Ct. Wayne County, Mich. July 10, 1973) (holding that psychosurgery could not be undertaken even on a consenting prisoner)); *Grimes*, 782 A.2d.

- 73. Id.
- 74. Id.
- 75. Id.

76. See Delgado & Leskovac, supra note 70, at 91-107 (noting that the interests of the patient and scientists are sharply opposed in the experimental setting); Feiler, supra note 12, at 2452 (noting that research embryos are more vulnerable than minor children and, therefore, should be protected after the potential harm to them is weighed against public detriment and researcher's interests); Carl Elliott, Pharma Buys a Conscience, 12 AM. PROSPECT, Sept. 24, 2001 (concerning the remarkable extent to which bioethicists and the medical community have permitted private corporate dollars to influence their research and judgment).

77. Feiler, supra note 12, at 2453.

78. Ultra-hazardous, non-therapeutic research on incompetent living humans also violates the Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, Council on Europe, art. 6(1), 17(2), ETS No. 164 [hereinafter Convention on Human Rights and Biomedicine].

79. Id. at 85.

80. Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001) (citing 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995) (finding that a state agency could not authorize non-therapeutic experiments on mental patients including both adult and minor subjects)). 81. *Id.* At some point, a risky nontherapeutic procedure could be deemed suicide.

82. Embryos are children only in the genetic sense that they are a result of fertilization of the parents' gametes and pragmatic sense that they are their parents' wards. The born human embryo is presumed the child of the birth mother. See Opportunities and Advancements Hearing, supra note 21, at n.16 and accompanying text (statement of JoAnn L. Davidson); see also In re O.G.M, 988 S.W.2d 473 (Tex. Ct. App. 1999) (finding that a male gametes provider was entitled to a grant of paternity in relation to a child born through IVF from a frozen pre-embryo conceived during marriage, but implanted in his former wife after divorce).

83. Roe v. Wade, 410 U.S. 413 (1973).

84. Roe, 410 U.S. at 413.

85. Robertson II, supra note 2, at 499 ("The constitutionality of state laws that seek to prevent the discard or destruction of IVF embryos does not depend on whether *Roe v. Wade* is reversed."); Parker, supra note 12, at 786-87. But see Doe v. Shalala, 862 F. Supp. 1421 (D. Md. 1994) ("The Court sees no distinction between fetuses in utero or ex utero.")

86. Robertson II, supra note 2.

- 88. Id. at 499.
- 89. Id. at 504-06.

90. Robertson II, *supra* note 2, at 446-47; *see also* Robertson I, *supra* note 2, at 972-75.

91. Robertson II, supra note 2, at 515.

92. 1995 WL 110368, at *4 (N.Y. Sup. Jan. 18, 1995) (unpublished), rev'd on other grounds, 663 N.Y.S.2d 581 (App. Div. 1997) (failing to reconsider trial court's endorsement of the view that embryos are more than property but less than persons). 93. 842 S.W.2d 588 (Tenn. 1992), cert. denied sub nom., Stowe v. Davis, 507 U.S. 911 (1993) (citing The American Fertility Society approving this position).

94. Davis v. Davis, No. E-14496, 1989 WL 140495, at *1 (Tenn. Ct. App. 1989), *rev'd*, 1990 WL 130807 (Tenn. Ct. App. 1990) (unpublished), *aff'd*, 842 S.W.2d 588 (Tenn. 1992), *cert. denied sub nom.*, Stowe v. Davis, 507 U.S. 911 (1993).

95. Davis, 1990 WL 130807.

96. Davis, 842 S.W.2d at 597. But see York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989) (treating the embryo as property).

97. Robertson I, supra note 2, at 782-83.

98. NIH Guidelines, *supra* note 7 (referencing 42 U.S.C. § 289g-1); Parker, *supra* note 12, at 781 (citing NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 50 (1999)).

99. Robertson II, supra note 2, at 510. It should be added that 21 C.F.R. § 1270.3 defines "banked human tissue" as "any tissue derived from a human body, which (1) is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease; (2) is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics; (3) is not currently regulated as a human drug, biological product, or medical device; (4) excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and (5) excludes semen or other reproductive tissue, human milk, and bone marrow."

100. See also Davis, 842 S.W.2d at 596 (finding that the Uniform Anatomical Gift Act, which governs fetal tissue, was "not precisely controlling" in relation to the human embryo).

101. See also Simkins v. Nevadacare, 229

^{87.} Id. at 487.

F.3d 729, 735 (9th Cir. 2000) ("We believe the average person would not...understand stem cells to be 'tissue.'").

102. PRIMER, supra note 56.

103. Id.

104. Id.

105. See Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (1999) (citing James A. Thomson et al., *Embryonic Stem Cell Lines* Derived from Human Blastocysts, 282 Sci. 1145 (1998)).

106. Thomson, *supra* note 105, at 1145 ("After undifferentiated proliferation in vitro for 4 to 5 months, these cells still maintained the developmental potential to form trophoblast and derivatives of all three embryonic germ layers....").

107. Ironically, Varmus insists that the investigation itself would be unethical. *Stem Cell Hearing, supra* note 33. ("It is true that sometimes these cells can aggregate and may appear like one of the early phases in the development of a normal embryo. But to my mind nothing would be less ethical than to attempt to ascertain whether or not this was indeed a precursor to an organism, a viable embryo....").

108. Mice studies prove that mice embryonic stem cells when implanted in the female give rise to a born mouse with the genetic make-up of the embryonic stem cells. See Andràs Nagy et al., Derivation of Completely Cell Culture-Derived Mice from Early-Passage Embryonic Stem Cells, 90 PROC. NAT'L ACAD. SCI. 8424 (1993). Experiments with cattle indicate that these results are not limited to mice. See Shizue Iwasaki et al., Production of Live Calves Derived from Embryonic Stem-Like Cells Aggregated with Tetraploid Embryos, 62 BIOLOGY REP. 470 (2000) (finding that the implantation of cattle embryonic stem cells into a host

leads to the birth of live cattle).

109. Nelle S. Paegel, Note, Use of Stem Cells Biotechnological Research, 22 in WHITTIER L. REV. 1183, 1188, 1190, 1203 (2001). Dr. Lee Silver, a mouse geneticist at Princeton University, has stated that, whereas he favors human embryonic stem cell research, "he is offended by the winking and nodding of scientists who do not want to admit the potential of the cells to become babies." Id. at 1203. Nagy, who created born mice from stem cells, added: "I don't think there's a theoretical or practical impossibility of creating а completely stem-cell derived human being, if one wanted to do that." Id. See also DIANE T. DUFFY, BACKGROUND AND LEGAL ISSUES RELATED TO STEM CELL RESEARCH 2 (Oct. 9, 2001) (CRS Report No. RS21044) (on file with authors) ("The earliest embryonic stem cells are called totipotent cells.").

111. 45 C.F.R. § 46.101(a) (2001) (emphasis added).

112. 45 C.F.R. § 46.102(f) (2001) (emphasis added).

113. 45 C.F.R. § 46.116 (2001) (emphasis added).

114. 45 C.F.R. § 46.116(b)(1) (2001) (emphasis added).

115. Robert Levine, The Boundaries Between Biomedical or Behavioral Research and Accepted and Routine Practice of Medicine, in 1 THE BELMONT REPORT, 1-6 (Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research ed., 1979).

116. Cf. 45 C.F.R. § 46.402(a) (2001) ("'Children' are persons...."). According to the Rabb memorandum, human stem cells do not qualify as "organisms" within the meaning of the term "embryo," as defined by the Dickey Amendment, because they are not "individual[s] constituted to carry

^{110.} Id.

out all life functions." Rabb memorandum, *infra* note 131, at 2. The necessary implication is that, by contrast, living human embryos are individuals able to carry out all life functions.

117. Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001).

118. Id.

119. T.D. v. N.Y. State Office of Mental Health, 650 N.Y.S.2d 173, 185, 192 (N.Y. App. Div. 1996). The New York Court of Appeals did not pass on the question of whether proxy consent of a child committed to a mental institution would have satisfied 28 C.F.R. Subpart D. *Id.* at 192.

120. Gross, *supra* note 4, at 862 (Subpart B is more on point, but "still fails to adequately address the complex issues raised by embryonic stem cell research.").

121. 45 C.F.R. § 46.201(a) (2001) (emphasis added).

122. 45 C.F.R. § 46.202(c) (2001).

123. 45 C.F.R. § 46.203 (2001).

124. Nat'l Inst. Health. Notice of Meeting of Panel, 59 Fed. Reg. 45,293, 45,293 (1994) [hereinafter Meeting of Panel] ("The Panel's charge encompasses only research involving the extracorporeal human embryo produced by in vitro fertilization, *i.e.*, in the test tube, or parthenogenesis.... Research involving in utero human embryos or fetuses is not part of the Panel's mandate. Guidelines for such research are embodied in...45 C.F.R. Part 46...."); Gross, supra note 4, at 862 ("Research on isolated stem cell lines, involving neither human sperm nor egg cells, does not meet the definition of IVF research.").

125. Meeting of Panel, *supra* note 124, at 45,293.

126. 45 C.F.R. § 46.201(a) (2001) (emphasis added). Notably, if the rest of

Aldous Huxley's prophecy becomes reality in the future, the totipotent living human embryo at an IVF clinic could be deemed an ex utero "fetus" subject to Subpart B. 45 C.F.R. § 46.209. Section 46.209 expressly "activities addressed directed toward fetuses ex utero, including nonviable fetuses, as subjects." Yet the definition of "fetus" in Section 46.202 is "the product of conception from implantation until а determination is made after delivery that it is viable" (emphasis added). The embryo which is the subject of human stem cell research has not been and will not be implanted and, thus, cannot currently qualify as a fetus. On the other hand, fetuses ex utero (more advanced than embryos) may theoretically exist in the future without implantation, rendering the definition of fetus in Section 46.202 unhelpful.

127. 45 C.F.R. § 46.111(a) (2001).

128. 45 C.F.R. § 46.102(i) (2001).

129. 45 C.F.R. § 46.111(b) (2001). For children, Subpart D of the Human Subjects Policy makes clear that federal funds can be expended on non-therapeutic research involving no more than "a minor increase over minimal risk." 45 C.F.R. § 46.406(a)(b)(2001).Additionally, 45 C.F.R. § 46.408 (2001) requires that IRBs solicit the assent of children to the research, unless the children are simply too young to give it and the intervention holds out a prospect of direct benefit to the children.

130. Consolidated Appropriations Act, Pub. L. No. 106-554, § 510(b) (emphasis added).

131. Memorandum from Harriet S. Rabb, General Counsel, U.S. Department of Health and Human Services, to Harold Varmus, Director, National Institutes of Health (Jan. 15, 1999) (on file with author).

132. See Balanced Budget Downpayment Act, Pub. L. No. 104-99, 110 Stat. 26, 34, Title I, § 128 (Jan. 26, 1996); Omnibus Bill, Pub. L. No. 104-208 § 512 (Sept. 30, 1996); Labor/HHS/Education Appropriations Act, Pub. L. No. 105-78 § 513 (Nov. 13, 1997); Omnibus Bill, Pub. L. No. 105-277 § 511 (Oct. 21, 1998); Omnibus Bill, Pub. L. No. 106-113 § 510 (Nov. 29, 1999); Omnibus Consolidated Appropriations Act of 2001, Pub L. No. 106-554 § 510 (Dec. 21, 2000).

133. Citing 45 C.F.R. § 46.208(a) (2) and section 489(b) of the Public Health Service Act (42 U.S.C. § 289g(b) (the risk standard for fetuses intended to be aborted and fetuses intended to be carried to term)).

134. See 65 Fed. Reg. 51976. The Rabb memorandum and, thus, the NIH Guidelines also stated that human embryonic stem cells are not "human as defined by the Dickey embryos," Amendment, on the grounds that they "are not organisms and do not have the capacity to develop into an organism that could perform all the life functions of a human being-in this sense they are not even precursors to human organisms." Id.

135. The authors wish to acknowledge the contribution of Gibson, Dunn & Crutcher LLP to this analysis of legislative history, which is partially reflected in the complaint that Human Life Advocates and Gibson, Dunn & Crutcher crafted in Nightlight Christian Adoptions v. Thompson, Civil Action No. 1.01CV00502-RCL, U.S. District Court, District of Columbia (March 8, 2001).

136. Although federal funding for IVF research projects was permissible, it required the approval of an Ethical Advisory Board (EAB). 45 C.F.R. § 46.204(d), nullified by section 121(c) of the NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (June 10, 1993). HHS declined to direct an EAB to perform any funding review of a proposed IVF research project until September 1978. That board concluded that certain funding was theoretically ethical, but the NIH declined to take any action on this conclusion. In early 1993, the Clinton Administration proposed, and Congress subsequently passed, legislation intended to eliminate the EAB approval prerequisite, as well as the executive moratorium on fetal tissue research. *Id.*

137. NAT'L INST. HEALTH, I REPORT OF THE HUMAN EMBRYO RESEARCH PANEL 49 (1994); see also id. at xvii, 2, 8, 26-27, 47, 49, 50, 76 (recommending federal funding for human embryonic stem cell research using "spare" embryos from IVF clinics).

138. 30 Weekly Comp. Pres. Doc. 2459 (Dec. 2, 1994) (on file with author).

139. Dep't of Labor, Health & Human Servs., Educ., and Related Agencies Appropriations for 1996: Hearings Before a Subcomm. of the House Comm. onAppropriations, 104th Cong., 1st Sess. 139, 144 (1995); see also NAT'L INST. HEALTH, BACKGROUND INFORMATION ON THE IMPACT OF THE HUMAN EMBRYO RESEARCH AMENDMENT 2 (1996) (The NIH would have funded six out of nine applications for grants involving embryo-related research "if the NIH had been able to proceed according to the [Human Embrvo Research Panel's] recommendations and the President's directive.").

140. H.R. REP. No. 104-209, at 384 (1996) (emphasis added).

141. Id. at 385.

142. 142 CONG. REC. S429, S433 (1996) (emphasis added).

143. H.R. REP. NO. 104-209, at 213-14 (1995).

144. *Id.* at H7364; 142 CONG. REC. H7339 (July 11, 1996).

145. Id. at H7339-43.

146. Id. at H7340 (emphasis added).

147. In a letter dated February 11, 1999, approximately seventy-five members of Congress requested that then-Secretary Shalala correct the HHS General Counsel's misinterpretation of the Dickey Amendment (on file with author). Paul Recer, Work Using Fetal Cells Draws Fire, BOSTON GLOBE, Feb. 18, 1999, at A10 (seventy Congressmen). On February 12, 1999, seven U.S. Senators added their disapproval (letter on file with author). The authors' review of the administrative record shows that the NIH received approximately 50,000 comments on the Draft Guidelines from members of Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens, the majority of which were opposed.

148. The House report language states, "The committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President." H.R. REP. No. 107-229, § 510 (2001). See also Azar memorandum, supra note 35.

149. H.R. 2059, 107th Cong. (2001) (killed in committee); S. 723, 107th Cong. (2001) (killed in committee); S. 1536, 107th Cong. § 510 (2001) (adding to the Dickey Amendment part (c): "Federal dollars are permitted, at the discretion of the President, solely for the purpose of stem cell research, on embryos that have been created in excess of clinical need and will be discarded, and donated with the written consent of the progenitors.")

150. Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act, 2002, Pub. L. No. 107-116 (Jan. 10, 2002).

151. Azar memorandum, supra note 35.

152. See Opportunities and Advancements Hearing, supra note 21, at n.19 (statement of JoAnn L. Davidson).

153. Parker, supra note 12, at 789.

154. FLA. STAT. ANN. § 390.0111(6) (West 2001) (prohibiting all research except that which preserves the life or health of the fetus); LA. REV. STAT. ANN. § 9:122 (West 2001) (banning all research on embryos and prohibiting the cultivation of embryos for the same); ME. REV. STAT. tit. 22, § 1593 (West 2001) ANN. (prohibiting all use of the product of conception in scientific research); MASS. ANN. Laws ch. 112, § 12] (Law. Co-op. 2001) (regulating the use of a live conceptus and banning non-therapeutic experimentation thereupon); MICH. COMP. LAWS ANN. § 333.2685 (West 2001) (banning non-therapeutic research on embryos, if that research substantially jeopardizes the embryo's life or health or if the embryo is the subject of a planned abortion); MINN. STAT. ANN. § 145.422 (West 2000) (banning all use of a conceptus in scientific research except where it is "harmless" to the conceptus); N.H. REV. STAT. ANN. § 168-B:15 (2000) (limiting the maintenance of non-frozen pre-embryos ex utero to fourteen days and prohibiting the transfer of a research preembryo to a uterine cavity); N.D. CENT. CODE § 14-02.2-01 (2001) (criminalizing the use of a fetus in experimentation where except the purpose is to determine/preserve the life or health of the fetus or mother); 18 PA. CONS. STAT.

ANN. § 3216 (West 2001) (criminalizing all non-therapeutic research on the conceptus); R.I. GEN. LAWS § 11-54-1 (2001) (prohibiting experimentation on all living embryos except as necessary for the life or health of the mother).

155. Forbes v. Napolitano, 236 F.3d 1009 (9th Cir. 2000), amended, 247 F.3d 903 (9th Cir. 2000) (Ariz. Rev. Stat. § 36-2302); Jane L. v. Bangerter, 61 F.3d 1493 (10th Cir. 1995), rev'd on other grounds sub nom, Leavitt Jane L., 518 U.S. 137 v. (1996)(overturning UTAH CODE ANN. § 76-7-310 ("Live unborn children may not be used for experimentation....")); Lifchez v. Hartigan, 735 F. Supp. 1361 (N.D. Ill. 1990) (overturning 720 Ill. Comp. Stat. § 510/6(7); See also Robertson II, supra note 2, at 503 (noting that at least twenty states have laws restricting fetal research and that, "[i]n many instances the statutes are drawn so broadly that they would apply to embryo research as well."). See, e.g., MO. REV. STAT. § 188.037 (2000); N.M. STAT. ANN. § 24-9A-1 to 7 (Michie 2001); S.D. CODIFIED LAWS §§ 34-14-16, 34-14-17 (Michie 2001); UTAH CODE ANN. § 76-7-31 (2001) ("Selling, buying, offering to sell and offering to buy unborn children is prohibited.").

156. FLA. STAT. ANN §§ 63.212(i)(2) (West 2001) provides that individuals may pre-planned adoption enter into а agreement wherein the mother agrees to become pregnant through "fertility techniques" including embryo adoption. The agreement must be reviewed and approved by a court of law to effect a final adoption. Id. LA. REV. STAT. ANN. § 9:126 (West 2001) requires "adoptive implantation" of embryos when the creators of the embryos are unidentifiable or no longer want the embryos. Embryo adoption is fulfilled when the couple "executes the notarial act of adoption of the ovum and birth occurs." LA. REV. STAT. ANN. § 9:130 (West 2000). See also OKL. STAT. tit. 10 § 556 (2001) (written consent of husband and wife desiring to receive and donate an embryo is necessary; the former statute also requires consent from a physician and any judge of a court having adoption jurisdiction in the state); TEX. FAM. CODE ANN. § 151.103 (West 2001) (written consent necessary of husband and wife desiring to receive embryo and of husband and wife desiring to donate embryo).

157. The compromise should not be merely administrative, because of the NIH's inherent conflict of interest as the regulatory agency enforcing the Human Subjects Policy. "On one hand, it will be overseeing oversight to ensure the fund recipients are following the guidelines. On the other hand, it's own scientists will be among those receiving the federal funds and competing in the marketplace with their results." Paegel, *supra* note 109, at 1198-99.

158. It makes little sense to us philosophically and theologically to treat any developmental stage of the human as less valuable than another or to distinguish the respect accorded the living human depending on its location within, partially outside, or completely outside the womb.

159. Some have argued that stem cells taken from living human embryos without the legally effective consent of their donors is to eat fruit of the poisonous tree. Of course, fruit of the poisonous tree doctrine stems from the Fourth Amendment and is applicable to embryonic stem cell research only by analogy. See Fourth Amendment Rights; Fruit of Poisonous Tree Doctrine, 29A AM. JUR. 2D Evidence § 752 (1994).

160. Consolidated Appropriations Act, Pub. L. No. 106-554, § 510(b) (emphasis added).

161. Rabb memorandum, *supra* note 131, at 2.

162. Accord DUFFY, supra note 109, at 2 ("The earliest embryonic stem cells...can develop into an entire organism, producing both the embryo and tissues required to support it in the uterus.").

163. Proposed revised permanent Dickey Amendment incorporating Bush Proposal: (a) None of the funds made available by this Act may be used for-(1) the creation of a human embryo or embryos for research purposes; (2)research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. §289g(b)); or (3) research that directly or indirectly involves or relates to [any cell or combination of cells derived directly or indirectly from] any cell line derived or obtained in any manner in which a human embryo or embryos were destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. §289g(b)); or that necessitates, entails, or creates the potential for the destruction of or injury to a human embryo [including without limitation any research involving or relating to any cell or tissue directly or indirectly obtained from or produced by any such cell line] except to the extent that such cell line was derived entirely (A) on or before August 9, 2001, (B) with the consent of the embryo's donors after full disclosure of the consequences of cell derivation, (C) from an embryo that was created solely for

reproductive purposes at a fertility clinic but subsequently deemed by the embryo's donors to be in excess of need, and (D) from an embryo that was donated for research purposes without the payment of any financial or other consideration to or on behalf of any donor or fertility clinic. (b) "Human embryo" is any organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

164. See European Council, Convention on Human Rights and Biomedicine Art. 18(2); Feiler, supra note 12, at 2466.

165. See Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. § 302 (2001); European Council, Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings Art. 1 (1998).

166. Concerning the embryo cyropreservation practice, see Opportunities and Advancements Hearing, supra note 21, at n.9 and accompanying text (statement of JoAnn L. Davidson). Robertson has argued, "IVF and freezing create and protect embryos; they do not destroy them." Robertson II, supra note 2, at 493. But the evidence suggests otherwise. Conservatively, 50% of the frozen human embryos perish the cyropreservation and thawing in process when one or more of their cells suffer cyroinjury. See Opportunities and Advancements Hearing, supra note 21, at n.17 and accompanying text (statement of JoAnn L. Davidson).

167. See LA. REV. STAT. ANN. § 9:130 (West 1991) (no embryo may be intentionally destroyed, and if IVF patients renounce their parental rights, the embryo shall be available for adoptive implantation); KY. REV. STAT. ANN. §

311.715 (Michie 1995) (public medical facility's intentional destruction of embryos shall be illegal). Robertson admits that IVF clinics are discarding embryos. See Robertson I, supra note 2, at 977 ("To avoid controversy with right-to-life groups and gain hospital approval, most American IVF programs claim to transfer all fertilized eggs to a uterus. However, many occasions will arise in which the gamete providers or others with decision-making authority over embryos will want to discard embryos.").

168. See Opportunities and Advancements Hearing, supra note 21 (testimony of J. Davis); Paul C. Redman II & Lauren F. Redman, Seeking a Better Solution for the Disposition of Frozen Embryos: Is Embryo Adoption the Answer? 35 TULSA L.J. 583 (2000).
The Ethics of Control

R. Alta Charo, J.D.**

In the beginning, there was the stem cell. While newspapers have primarily focused on this solitary cell, caught in a swirling debate about medical potential and research funding, others have come to recognize the larger struggle at hand-a struggle over the control of reproduction and human biological materials. Indeed, only days after the Bush Administration announced its support for limited federal funding for research on embryonic stem cells, legislators in Wisconsin, the epicenter of embryonic stem cell research, announced their intention to introduce legislation that looks more broadly at the infertility services that have led to the glut of "surplus" embryos destined for destruction and eyed with interest by stem cell researchers.¹ And less than three months later, some U.S. senators found themselves trading their desire to increase federal embryonic stem cell funding for a withdrawal of a bill to criminalize reproductive and research cloning.² This deal, however, was threatened when a Massachusetts company announced partial success at generating human embryos through cloning,3 triggering renewed calls for Senate action to ban research cloning.⁴ But if this debate is less about the ethics of research on stem cells and more about the ethics of the reproductive control that, among other things, yields the embryos from which the stem cells are obtained, then how can one understand the forces that shape public attitudes?

Toward the end of Simon Mawer's novel, *Mendel's Dwarf*, the protagonist, a hereditary dwarf, faces a choice: "Benedict Lambert is sitting in his laboratory playing God. He has eight embryos in eight little tubes. Four of the embryos are proto-Benedicts, proto-dwarfs; the other four are, for want of a better word, normal. How should he choose?"⁵ How indeed? How should he decide which of the embryos to use to make his child?

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[†] An earlier, unannotated version of this piece appeared as R. Alta Charo, Are We Playing God? Or Playing Human?, WASH. POST, Aug. 12, 2001, at B1.

Whether in the debates over human reproduction or over embryonic stem cell research, again and again the public debates whether it is wrong to "play God."⁶ But what does this mean? If a couple decides to destroy one of its embryos, would that be playing God? Or if a cell taken from the inside of the mouth is cloned to make an embryo for research use, is that crossing the line?

President Bush seems to draw that line somewhere in between. On August 9, 2001, he endorsed federal funding for research on stem cells derived from embryos that are now long dead, but said he would not endorse government-financed research on cells derived from embryos yet to be killed or those made specially for research purposes.⁷ Citing his own prayer and reflection, as well as America's diversity of faith, he said, "Human life is a sacred gift from our creator," and "[w]e recoil at the idea of...creating life for our convenience."⁸ These conclusions led him to a compromise, he said, one that limits the government's entanglement with acts that involve creating embryos but permits it to benefit from destroying them, at least if that act of destruction happened some time ago and is beyond our—and God's—ability to alter.⁹

In a country pledged from its formation not to endorse a single faith, a country in which the decennial census shows ever-increasing diversity of faith—and lack of faith—in the population, how can people reach a consensus about government policies on stem cell research while differing on views as fundamental as whether it is righteous duty, heretical defiance, or mere scientific inevitability to exercise control over things as fundamental as life and death?¹⁰

The President would seem to view control over creation and destruction of an embryo as an unacceptable act of human hubris, a view shared by many Christian theologians. During a 1997 consideration of cloning policy, for example, the National Bioethics Advisory Commission (NBAC) heard similar testimony. Its members listened as theologian Dr. Gilbert Meilaender testified that Protestants, although stout defenders of human freedom, nonetheless "have not located the dignity of human beings in a self-modifying freedom that knows no limit, [not] even...God."¹¹ Rev. Albert Moraczewski, a Catholic, testified that cloning "exceed[s] the...delegated dominion given to the human race. There is no evidence that humans were given the power [by God] to alter their nature or the manner in which they come into existence."¹²

So what should Benedict do? Should he refuse to choose, because choosing is an act of God, an act that exceeds his delegated dominion over life? Benedict's instinct about God's role is in fact somewhat different:

Of course we all know that God has opted for the easy way out. He has

decided on chance....You may...select two of the four normal embryos and send them over to the clinic for implantation...or...select the four achondroplastics, the four stunted little beings...and send them over instead...or...refuse to usurp the powers of God and choose instead to become as helpless as He...by choosing one normal embryo and one achondroplastic and leaving the result to blind and careless chance.¹³

When fertile couples have intercourse, sometimes an egg is fertilized. At times, the uterine lining catches that fertilized egg, and it develops into a baby. At other times the fertilized egg slides past that lining and is washed away in menstrual blood, unnoticed and unmourned at the end of the month. Should infertile couples whose embryos rest in laboratory dishes rather than the womb be similarly careless, rolling dice to decide whether to use or destroy them? Or are they—as is our government—obliged to take control and ensure that each and every embryo is placed in the body at just the right time to maximize the chance of gestation and beat the natural odds? If the latter, then, should this action, this defiance of the natural order of chance and luck, also suggest the option to choose not to use the embryo, but instead to donate it for potentially life-saving research?

It is evident that Americans do not share a common view on the act of choice where creating life is concerned, and that is why the stem cell issue is so difficult. While some see choosing as "playing God,"¹⁴ others see it as "playing human."¹⁵ Indeed, Rabbi Elliot Dorff testified at that same NBAC meeting that we are "the partner of God in the ongoing act of creation. We are God's agent....The [Jewish] tradition has not been passive in terms of simply accepting whatever medical cards we have been dealt."¹⁶ Examining Biblical texts, Rabbi Moshe Tendler testified that being such a partner means taking an active role, and that "artificiality," far from being wrong or evil, is rather a sign of humanity's constructive contribution, a sign that we are doing our duty.¹⁷ Furthermore, a professor of Islamic studies, Aziz Sachedina, described how the Koran suggests that "as participants in the act of creating with God, God being the best of creators, human beings can actively engage in furthering the overall state of humanity by intervening in the works of nature, including the early stages of embryonic development" when the goal is to achieve a natural good, such as health or fertility.¹⁸

For those who view acts of reproductive control as heretical, it is difficult to tolerate the waste that accompanies modern infertility care, its laboratories filled with frozen surplus embryos that are no longer wanted by anyone. But it becomes almost insurmountably galling to them to be asked to pay for research using stem cells derived from some of these embryos, even if the embryos would have been destroyed anyway, and even if their tax dollars will not be used in any way to help or hasten that destruction. For many opponents of stem cell research, publicly funded research makes every taxpayer unwillingly complicit in the underlying, immoral choice to destroy the embryo.¹⁹ It matters not that most would not hesitate to accept organ donation from the victim of a carjacking and murder; while they might mourn the necessity of finding their own lives saved through the death of another, in no way would they feel that their acceptance of this gift of life made them complicit in the underlying brutality of the victim's death.

Where embryonic stem cells are concerned, however, the sense of complicity persists. Perhaps it is because the embryos, while already doomed, are viable until their stem cells are removed, raising images of state-sanctioned execution by disembowelment. Or perhaps it is simply because opponents fear becoming complicit, not in the act of embryonic destruction itself, but in a culture of tolerance for embryonic destruction, a culture that might become increasingly comfortable with balancing the needs of the born against the needs of the embryo, a culture that balances not only the needs of patients against embryonic loss, but also the needs of scared teenagers or impoverished women with unwelcome pregnancies.

There are, of course, broader implications of the President's decision. He cited not only the diversity of faiths in the United States and the diversity of opinions within those faiths, but also the diversity of experience in this country with the illnesses that might best be cured by research with embryonic stem cells. "I have friends whose children suffer from juvenile diabetes," Bush said. "Nancy Reagan has written me about President Reagan's struggle with Alzheimer's. My own family has confronted the tragedy of childhood leukemia."²⁰ This visceral, intimate knowledge of the interests held in the balance led him to approve limited funding because of the responsibility, in his words, to juxtapose "the need to protect life in all its phases with the prospect of saving and improving life in all its stages." Should this not lead him to consider, then, whether other people's visceral, intimate knowledge of the ravages of birth defects, unwanted pregnancy, or infertility makes an equally compelling case for tolerating embryonic loss and enhanced reproductive control? Indeed, does his decision not commit him to a position long considered pro-choice: that the needs of those already born must be balanced against our regard for embryonic and fetal life, and that the people entitled to decide what happens to an embryo are not those in government but those whose gametes were used to create it?²¹

Philosopher Thomas Nagel wrote that "Morality's ambition is, or at

least ought to be, to provide a system of conduct under which everyone can live with a sense of mutual justifiability. This follows from the conditions of political legitimacy.^{"22} A democracy consists of more than voting once a year. It consists of ensuring that all those voters and their elected representatives identify with both the peril and potential of each policy choice. This is why there is hope to be found in the extended public deliberation on embryo and stem cell research. Even its opponents will partake in the cures that may be found for juvenile diabetes, Alzheimer's disease, Parkinson's disease, heart disease, and spinal cord injuries. Few, one suspects, would pledge to forever forego such treatments because of their origins.²³ The medical treatments they may receive will likely not be sufficient to overcome their personal objections, but it does ensure that they will not be politically insulted solely on behalf of the interests of others; their interests, too, are promoted by this research.

This concern about the distribution of burdens and benefits of policy choices represents something larger than the more narrowly focused debates about the morality of stem cell research, abortion, euthanasia, or any number of divisive practices. It is an indication that Americans are united more by a shared desire for fair governance than divided by respective disappointments in the particular stem cell research policy adopted through that governance. And it is a sign that the policy choices created by advances in the biomedical sciences may be resolved by supplementing attention to traditional bioethics with some attention to political ethics and a philosophy of governance that insists upon leaving no one social group with the burdens but not the benefits of a policy choice, and no one political movement with the desire but not the political access to alter it.²⁴

In many ways, the compromise crafted by the Bush administration concerning stem cell funding features these characteristics of political legitimacy. By limiting funding to existing cell lines derived from longdead embryos,²⁵ the arguments about complicity are moved away from images of the executioner and toward the images of organ donation.²⁶ Funding also enables research on alternative, less controversial forms of stem cells, so that parallel experimentation ensures that if other sources ever become an adequate substitute,²⁷ research on embryonic sources can be forgone and gratuitous offense avoided.²⁸ At the same time, its insistence on using only a limited number of cell lines²⁹ (a limit that many scientists fear will delay research that might otherwise save the lives of people already sick today³⁰) may not be supportable in the long run,³¹ premised as it is on a particularly personal vision of the role of humanity and of God. The furor over embryonic stem cell research, in general, and research on cloning in particular, puts one in mind of earlier conflicts between the needs of science and the sanctity of the body—dead, alive, or yet to be conceived. Although physicians in ancient Greece were permitted to dissect the bodies of foreigners, dissection of Greeks was unthinkable.³² Indeed, for most of the medieval era in Europe, dissections were forbidden because of the Church's view that the human body was God's province. It was not until the thirteenth century that strictly limited and controlled dissection was permitted at universities, and even then the practice continued to represent an uneasy truce between cultural taboos and scientific advances.³³

Each generation debates the limits of what can be done to the human body and reaches its own conclusions.³⁴ And in every era, some scientist feels compelled to test those limits in the name of knowledge. In the current era, that debate will continue under the auspices of yet another federal body set up to consider the perils and potentials of biomedical advances—the President's Council on Bioethics, which Bush announced on August 9th.³⁵ Its chairman, Leon R. Kass of the University of Chicago, has made his views on research cloning for stem cell retrieval rather clear. Within days of the announcement that human embryos had been cloned for this purpose, speaking on a national news program, he said:

The Congress of the United States by a margin of over 100 votes, including 60 Democrats, enacted legislation [sic]³⁶ designed to stop all human cloning from the very start. Here we have a group of entrepreneurs who, for their own good reasons and confident that their good intentions are sufficient unto the day, crossed this line in defiance of all of these things. I don't think that's the right way for us to proceed.³⁷

He has also said that the mandate of the President's Council on Bioethics will go beyond merely monitoring stem cell research and will extend to a comprehensive public discussion of how to embrace the promise of biomedical advances without losing sight of "human decency, human dignity, and respect for life."³⁸ Concerns, however, have already been expressed about what meaning the new Council's chair will attribute to this phrase, as his previous writings have consistently expressed skepticism about the wisdom of things as varied as in vitro fertilization, autopsies, and the feminist movement.³⁹ Those concerns have mounted with the appointment of Dean Clancy, a conservative policy aide to Rep. Dick Armey, as the new executive director.⁴⁰ Clancy is known not only for his opposition to constitutional protection for abortion rights,⁴¹ but also for advocating, amongst other things, a repeal of the Seventeenth Amendment,⁴² which provides for the direct election of United States Senators, and for the elimination of all public funding for schools.⁴³

John Adams once wrote, "This country has done much, I wish it may do more, and annul every narrow idea in religion, government and commerce."⁴⁴ The President and the chair of the new Council on Bioethics are surely, like all Americans, entitled to their personal faith and vision. But should the day come when that vision is shown to be too narrow to accommodate the needs of research on behalf of all Americans,⁴⁵ one hopes that the vision may broaden to encompass the diversity of all human experience and all human faiths. One hopes that government policies will continue to evolve to protect the interests of all citizens.

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5. SIMON MAWER, MENDEL'S DWARF 238 (1998).

6. Sheryl G. Stolberg, *Bioethicists Find Themselves the Ones Being Scrutinized*, N.Y. TIMES, Aug. 2, 2001, at A1.

7. Press Release, Office of the Press Secretary, White House, *Remarks by the President on Stem Cell Research* (Aug. 9, 2001) [hereinafter *Bush*], http://www.white house.gov/news/releases/2001/08/200108 09-2.html. The policy will require researchers to use only cells collected from embryos created for reproductive-rather than research-purposes, and donated without compensation and with informed consent. Most importantly, the embryos must have been destroyed before the President's announcement. His goal was to eliminate not only the remote possibility that future decisions to discard embryos might be influenced by the prospect of federal support for research on stem cells derived from them. but also the appearance that such influence might exist. The President said that approximately sixty lines of the cells existed worldwide the time of his at announcement. He reiterated his position on research cloning and, indeed, extended it to endorse a prohibition not only on government financing of the technique, but also on privately financed efforts to develop cloned human embryos for stem cell retrieval and research. See also Bush Says Cloning Is Morally Wrong, Urges Congressional Ban, BULLETIN'S FRONTRUNNER, Nov. 27, 2001.

8. The Bush Administration policy requires not only that the stem cells were harvested prior to August 9, but also that they were derived from embryos left over from fertility procedures-as opposed to having been created solely for the purpose of stem cell retrieval-and that they have been obtained without inducement and with the informed consent of the progenitors. The informed consent requirement, ironically, was loosened by Bush Administration policy. After the Clinton Administration removed the regulatory obstacles that had created a de facto moratorium on federal support of research on embryos, the National

Institutes of Health (NIH) appointed a Embryo Research Panel Human to recommend guidelines for its grants. See R. Alta Charo, The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women, 6(2) STAN. L. & POL'Y REV. 1 (1995). That panel recommended spending federal money on research on discarded, surplus embryos and on a carefully delimited range of experiments that would require the use of so-called research embryos-that is, embryos created specifically for research. The Clinton Administration announced its opposition to the latter recommendation, but before the NIH could act on the remaining recommendations, Congress enacted a series of legislative prohibitions on the use of federal money for research that destroyed embryos, and the panel's recommendations became moot. Partly in response, the NIH issued guidelines for research on human embryos that detailed the permissible uses of embryos, the consent process, and what documentation would be needed. See National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000). Those guidelines required that the cell lines be derived from embryos that had been frozen before being discarded, in order to ensure that they were not needed for reproductive purposes and that they had been given to researchers after the donors had some period of time for reflection. President Bush was forced to avoid endorsing that requirement, lest an inordinate number of the existing cell lines turn out to be ineligible because they had been derived from fresh, rather than frozen, embryos. To that extent, the new policy retreats from the most conservative view of informed consent for donation.

9. Additional details of the human subjects research regulations that will apply to embryo and stem cell research have been announced. See OFF. HUMAN RES. PROTECTIONS, DEP'T HEALTH & HUMAN SERVS., GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS AND CELL-DERIVED TEST ARTICLES (Nov. 16, 2001), http:// ohrp.osophs.dhhs.gov/references/HESCG uidance.pdf.

10. Religious leaders have made varying statements on whether their particular denominations or religions can support stem cell research and, more specifically, research cloning to generate stem cells. Many Christian denominations have voiced opposition, while others remain silent; Jewish groups have been either supportive or silent; and Islamic groups are still working to reach a consensus. See Press Release, Associated Press, Religious Leaders Split on Cloning (Nov. 27, 2001) (on file with author).

11. NAT'L BIOETHICS ADVISORY COMM'N, MEETING TRANSCRIPT 185 (Mar. 13, 1997), http://bioethics.georgetown.edu/nbac/tra nscripts/1997/3-13-97.pdf.

12. Id. at 152.

13. MAWER, supra note 5, at 238-39.

14. Stolberg, supra note 6, at A1.

15. Helen T. Gray, Ethicists, Theologians and Clergy Urge Caution in Development of Cloning Technology, KAN. CITY STAR, Mar. 8, 1997, at E1.

16. NAT'L BIOETHICS ADVISORY COMM'N, MEETING TRANSCRIPT 9 (Mar. 14, 1997), http://bioethics.georgetown.edu/nbac/tra nscripts/1997/3-14-97.pdf.

17. *Id.* at 17.

18. Id. at 51.

19. R. Alta Charo, Embryo Research: An Argument for Federal Funding, 4(6) J.

WOMEN'S HEALTH 603, 603-08 (1995).

20. Bush, supra note 8.

21. AM. LIFE LEAGUE, ANALYSIS OF PRESIDENT GEORGE W. BUSH'S STEM CELL DECISION ("In summary, through the use of his carefully weighed rhetoric, the President consistently worked to undermine the fundamental, irrefutable scientific fact at the core of this issue: that human life begins at conception/fertilization and that there is never an acceptable reason for intentionally taking an innocent human life. While even supposedly presenting the pro-life perspective in portions of his presentation, he used terms such as 'potential life,' 'cluster of cells,' 'seeds,' 'byproduct,' and strategically omitted 'human' in key places serving to obfuscate these scientific and ethical realities."), http://www.all.org/news/index.htm.

22. Thomas Nagel, Moral Epistemology, in SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISIONMAKING IN BIOMEDICINE 201, 212 (Ruth Bulger et al. eds., 1995).

23. Richard Doerflinger, spokesperson for the U.S. Conference of Catholic Bishops, in personal communication with the author on November 9, 2001, remarked that some people have made just such a pledge, but that in general no such pledge would be demanded of embryonic stem cell research opponents. It is likely that they will face situations in which, due to evolving funding policies in this area, the only therapy that has been developed is one that is based upon the unacceptable research.

24. For a more extended discussion of political ethics as a tool to resolve bioethics debates, *see* Charo, *supra* note 8.

25. NIH's Human Embryonic Stem Cell Registry (http://escr.nih.gov/) lists the entities that have developed stem cell lines meeting the President's criteria for federal funding.

26. Press Release, National Right to Life Committee (Aug.10, 2001) http://www.nrlc.org/killing_embryos/inde x.html. ("While we mourn the lives of those children that were killed to derive the sixtyplus stem cell lines that currently exist, there is nothing that we, as a pro-life community, or President Bush can do to restore the lives of those children. Neither President Bush nor the federal government had anything to do with the destruction of those embryos or the establishment of those cell lines. Certainly, if the President could have prevented the death of those embryos, he would have. President Bush has shown his commitment to protecting the lives that he can.").

27. Another possible source might be embryo-like entities that provide stem cells but are not viewed by opponents as having the same moral status as an embryo. One such possibility would be parthenotes (i.e., embryo-like entities created through parthenogenesis rather than fertilization or cloning). Richard Doerflinger, in personal communication with the author on November 9, 2001, said that if the parthenotes are simply non-viable embryos, then opposition would remain unchanged. See Andrew Pollack, New Work May Provide Stem Cells While Taking Baby from Equation, N.Y. TIMES, Nov. 6, 2001, at F3. This is because such embryos would be, roughly speaking, the equivalent of a terminally ill person, upon whom destructive research is still forbidden. However, if the parthenotes are merely pluripotent (i.e., capable of giving rise to most tissues of an organism), rather totipotent (i.e., than having unlimited capability, including the capacity specialize extra-embryonic to into membranes and tissues, the embryo, and

all post-embryonic tissues and organs), they might not be seen as having the same moral status as an embryo and could become an acceptable source for stem cells.

28. Another significant aspect of the President's announcement for researchers is its potential to decentralize stem cell research in the United States. Prior to his decision, scientists were uncertain about administration how the Bush would interpret congressional actions since 1996 that prohibit the use of federal funds for research that involve the destruction of embryos. Congress never specifically prohibited spending money to study cells from embryos that had been destroyed using private funds. Nonetheless, that uncertainty had an effect on early research on human embryonic stem cells. Scientists worried that the Administration might decide that, because of shared overhead costs, conducting research on embryonic stem cells with private money in a facility that also houses federally financed research constitutes a use of federal dollars. To avoid that possibility, the University of Wisconsin at Madison, for example, helped James A. Thomson to develop a separate research facility for his work that led to the creation of the first sustainable line of human embryonic stem cells. The sizable investment required for the creation of separate laboratories presented an obstacle to other universities that might have been pleased to see their scientists accept private funds for embryonic stem cell research. Bush's announcement, however, With comes the possibility of removing the uncertainty. Depending on how the NIH interprets the President's policy and how it interprets the significance of shared overhead, the result may be a blossoming of privately supported research on

campuses that no longer need to consider the development of separate facilities as part of the start-up costs.

29. Stem Cell Research, Hearing Before the Senate Comm. on Health, Educ., Labor, and Pensions, 107th Cong. (2001) (statement of Tommy Thompson, Secretary, Department of Health and Human Services) (admitting that more than half of the existing cell lines made eligible for federal research monies under the President's policy had yet to be fully characterized as embryonic stem cell lines).

30. It should be noted that some scientists have also expressed concern that the President's policy will force researchers to rely solely on patented stem cell linesand to pay licensing fees. Such concerns are misplaced. First, the basic patents cover lines already in existence and those to be developed, so whether a researcher wishes to use federal money and study existing lines or to use private funds and study future lines, the issues concerning patents remain the same. Second, patent holders like the University of Wisconsin have already made arrangements to ensure wide access to the lines, including very low licensing fees for academic researchers, and to ensure that researchers can freely patent-their share-and even own discoveries made through stem cells. See Press Release, National Institutes of Health, National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement (Sept. 5, 2001), http://www. nih.gov/news/pr/sep2001/od-05.htm.

31. Indeed, administration officials announced a few days after the President's August 9 speech, regardless of the scientific results of the work with existing lines, the government would not support research on other lines in the future. See Sheryl G. Stolberg, U.S. Acts Quickly To Put Stem-Cell Policy in Effect, N.Y. TIMES, Aug. 11, 2001, at A1: Press Release, Sharon Theimer. Associated Press, Thompson: Bush Firm on Stem Cells (Aug. 12, 2001) (on file with author). Many scientists fear that the existing lines either may not be capable of producing all other kinds of cells or may not be robust and diverse enough to support their work. Nonetheless, a number of scientists have expressed relief that at least some funds will be available. See Sheryl G. Stolberg, The Basic Research: A Science in Its Infancy, but with Great Expectations for Its Adolescence, N.Y. TIMES, Nov. 27, 2001, at A12; Robin Toner, The Reaction: Each Side Finds Something To Like, and Not, N.Y. TIMES, Aug. 10, 2001, at A1; Rick Weiss, Promising More—and Less, Scientists See Growth in Field, WASH. POST, Aug. 10, 2001, at A1.

32. Gordon Grice, Slice of Life; How a Convicted Killer's Corpse Brought Anatomy into the Digital Age, NEW YORKER, Jul. 30, 2001, at 36.

33. Id.

34. The same, of course, is true for each nation and each region. The United Kingdom banned reproductive cloning, while permitting research for stem cell retrieval, and the European Union has failed to pass a proposed ban on research cloning. See Stephen Castle, European MPs Refuse То Outlaw Human Cloning, INDEPENDENT (LONDON), Nov. 30, 2001, at 18; Greg Hurst, MPs Pass Bill to Forbid Cloning, TIMES (London), Nov. 30, 2001; Michael Kallenbach. MPs Worried by 'Panic Legislation' Human Cloning, DAILY TELEGRAPH (London), Nov. 30, 2001, at 18); Press Release, Associated Press, Brits OK Ban on Creating Human Clones (Nov. 30, 2001) (on file with author). On the other hand, Germany is well known for its strict limits on embryo research generally. See Steven Kamarow, Germany Awaits U.S.

Action on Stem Cells: Controversial Research Is Testing Moral Lessons from Hitler's Reign, USA TODAY, Aug. 9, 2001, at 5A. France, Austria, and Ireland also ban or strictly limit embryo research, while Sweden permits it generally. Denmark permits it for infertility research, and many other European countries have no domestic law on the subject. See Press Release, World Reacts to U.S. Stem Cell Plan (Aug. 10, 2001) (on file with author). A number of Asian countries are predicted to be relatively open to embryonic stem cell research, including research that used stem cells from cloned embryos, in part because Buddhist tradition does not explicitly condemn the practice. Associated Press, Asia Could Emerge as Stem Cell Leader (Dec. 23, 2001).

35. George W. Bush, Executive Order: Creation of the President's Council on Bioethics (Nov. 28, 2001), http://www. whitehouse.gov/news/releases/2001/11/2 0011128-13.html.

36. It was the House, not the full Congress, that so voted; and while the bill passed in the House, no legislation will be passed until the Senate similarly acts and a bill is signed by the President.

37. Newshour with Jim Lehrer: Interview with Leon Kass (PBS television broadcast, Nov. 26, 2001).

38. Face the Nation: Interview with Leon Kass (CBS television broadcast, Aug. 12, 2001). For selected writings by Leon Kass, see http://www.alteich.com/links/kass.htm. This expansive view is reflected in the Charter for the Council, announced by the President. Executive Order: Creation of the President's Council on Bioethics, Nov. 28, 2001, at http://www.whitehouse.gov/ news/releases/2001/11/20011128-13.html.

39. Chris Mooney, Irrationalist in Chief, 12 AM. PROSPECT 10, 10-13 (2001).

40. Arthur Allen, Back to Nature (Nov.

30, 2001), http://www.salon.com/ mwt/feature/2001/11/30/bioethics/index .html?x; Press Release, Department of Health and Human Services, *Clancy Named Executive Director of National Bioethics Council* (Nov. 30, 2001) (on file with author).

41. Dean Clancy, *The Constitution's Not* the Thing, NAT'L REVIEW, Dec. 31, 1999.

42. Dean Clancy, *Forbes in 2000*?, J. AM. CITIZENSHIP POL'Y REV., Jan./Feb. 1998, at Correspondence 3.

43. See The Separation of School & State Alliance, at http://www.sepschool. org, for a list of signatories, Dean Clancy among them, for an organization advocating an end to public funding of schools. Clancy's support is noted as important and singular among government officials during a discussion by another organization allied with the Alliance. See also Interview with Marshall Fritz, Of the Separation of School & State Alliance 1999). http://www. (Iune 3. at homeschoolchristian.com/ChristianEd/Fri tz.html.

44. DAVID MCCULLOUGH, JOHN ADAMS 631 (2001).

45. In a development closely related to stem cell research, scientists were dismayed when the House of Representatives voted on July 31 in favor of H.R. 2505, the Human Cloning Prohibition Act. The bill includes a provision that would make it a crime to use cloning technology to make embryos for research purposes. Legislators have chosen to ignore both the fact that it would be possible to use other means to prevent the birth of children conceived through cloning-for instance, prohibiting the transfer of a cloned embryo into a woman's body-and the long history of embryos through in vitro creating fertilization for research on how to infertility treatments. improve It is

interesting to note that, to date, Congress yet to comprehensively regulate has medical experiments on children or adults-let alone make any aspects of them a crime. Instead, the government relies on conditions attached to the receipt of federal funds for research or approval by the Food and Drug Administration (FDA) of resulting products, as well as a system of compliance with federal voluntary standards by large research institutions even where federal funds or FDA approval are not at issue. But research supported by private funds that is not covered by those regulations can be conducted without fear of federal penalty, although state laws and the rules of professional societies may restrict it. The NBAC has called for federal legislation in that area, and bills to regulate such research have recently been introduced in Congress. So far, however, human research generally remains by federal law. See NAT'L untouched BIOETHICS ADVISORY COMM'N. ETHICAL AND ISSUES INVOLVING HUMAN POLICY PARTICIPANTS (2001). If the House bill on cloning becomes law, it would create significant federal limits on what some scientists consider an important and promising area of research before federal protections have been enacted to regulate research on people generally.

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An Ethical Defense of Federal Funding for Human Embryonic Stem Cell Research

James F. Childress, Ph.D.**

Should the Federal Government fund human embryonic stem cell research? In addressing this question and answering it affirmatively, I will draw from testimony I was asked to prepare for the Hearing on "Stem Cell Research" conducted by the U.S. Senate Committee on Health, Education, Labor and Pensions, chaired by Senator Edward M. Kennedy, on September 5, 2001. Even though I did not testify on that occasion on behalf of the National Bioethics Advisory Commission (NBAC), on which I served until its demise at the end of September 2001, I drew, then as well as now, on the NBAC's 1999 report on *Ethical Issues in Human Stem Cell Research*, which, as a commissioner, I helped to prepare and also endorsed.¹

I. A RANGE OF ETHICALLY ACCEPTABLE POLICIES

Despite the thought and consideration that went into President Bush's announced policy on the use of federal funds in human embryonic stem cell research, I would argue that more flexible policies are ethically acceptable and even preferable. Three options merit consideration:

(1) Providing federal funds for research on cell lines derived (using nonfederal funds) from embryos prior to August 9, 2001 within certain ethical guidelines (President Bush's announced policy).

(2) Providing federal funds for research on cell lines derived (using non-federal funds) from embryos, earlier or in the future, within certain ethical guidelines (the policy proposed earlier by the National Institutes of Health (NIH)).

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(3) Providing federal funds for both the derivation of, and research on, cell lines derived from embryos within certain ethical guidelines (NBAC's recommendation).

President Bush's announced policy (option 1) suggests that it is ethically acceptable to use federal funds for research on stem cell lines that were derived, using non-federal funds, prior to his announcement on August 9, if the derivation also met certain ethical requirements, including the informed consent of donors of embryos created solely for reproductive purposes and the absence of financial inducements.² If policy option 1 is ethically acceptable—as I believe it is—then it should also be ethically acceptable to do the same thing prospectively (policy option 2). That is, it should be ethically acceptable to provide federal funds for research on stem cell lines derived in the future, after August 9 as well as before, with non-federal funds and within the same ethical guidelines. This prospective policy would offer greater—and needed—flexibility for the short-term and long-term future. And it would be ethically preferable because it would increase the possibilities for important research, without violating relevant ethical standards.³

President Bush's statement noted that the first policy (option 1), which includes about sixty stem cell lines (about which there is considerable scientific uncertainty and controversy⁴), "allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."5 However, I believe that ethically we can provide federal tax funds for research on stem cells derived after as well as before August 9, using non-federal funds, and that this can be accomplished without sanctioning or encouraging further destruction of human embryos. To do so, we must establish effective ethical safeguards. Those safeguards should ensure, to the greatest extent possible, the couple's voluntary and informed decision to destroy their embryos-rather than use them or donate them to another couple-and their voluntary and informed decision to donate them for research. Each decision should be free of financial inducement. In view of the couple's decision to destroy the embryos, the research would only determine how the destruction occurs, not whether it will occur; as matters stand in most jurisdictions, couples may determine how to dispose of their embryos.

It is possible to go further than either of these first two policies and recommend, as the NBAC did, a third option—the provision of federal funds for both the derivation of stem cells from embryos and research on those cell lines, again in accord with ethical requirements. One argument for this option is that a strict separation between derivation and use would adversely affect the development of scientific knowledge. For instance, the methods for deriving embryonic stem cells may affect their properties, and scientists may increase their understanding of the nature of such cells in the process of deriving them.⁶

In short, I see no ethical reason for limiting federal funding to research with cell lines derived by some arbitrary date, as long as we can ensure that future derivation, with non-federal funds (option 2) or federal funds (option 3), also respects the same moral limits. Indeed, our collective moral duty to alleviate human suffering and reduce the number of premature deaths provides a strong ethical reason to support this research, within moral limits.

II. RESPECT FOR THE EMBRYO

There is widespread agreement, as the NBAC observed, that "human embryos deserve respect as a form of human life," but at the same time, sharp disagreements exist "regarding both what form such respect should take and what level of protection is required at different stages of embryonic development."⁷ At the very least this "respect" implies that:

- Early embryos should not be used unless they are necessary for research;
- embryos remaining after in vitro fertilization (IVF), as well as cadaveric fetal tissue, should not be bought or sold; and
- alternative sources of stem cells should simultaneously be explored.

Indeed, given the promise of this research, and the uncertainty about which stem cells might be adequate and which might be superior for various purposes, research on stem cells derived from different sources should be eligible for federal funding. The goal of realizing the therapeutic promise of stem cell research is ethically significant. It is also ethically important to treat the different sources of stem cells with appropriate respect.

One interpretation of appropriate respect for early embryos would rule out their deliberate creation in order to use them in research. I supported the NBAC's recommendation that, at this time, federal agencies should not fund research involving the derivation or use of embryonic stem cells from embryos made solely for research purposes, whether they were made by IVF or by somatic cell nuclear transfer into oocytes. However, in this area, it is ethically dangerous to say "never," and the Senate should not accept the House ban on so-called "therapeutic cloning" (in contrast to "reproductive cloning"). For now, it appears to be possible to develop enough cell lines without creating more embryos, and there appears to be no need for nuclear transfer unless and until therapy is possible. But if therapy becomes possible, matched tissue may be needed. And it may then be necessary to revisit the question about so-called "therapeutic cloning,"⁸ which at the present is really experimental research rather than therapeutic.

III. DIVERSITY OF RELIGIOUS AND SECULAR VIEWS

Views about appropriate respect for the embryo hinge on convictions about the embryo's moral status. As a specialist in religious ethics, I have been fascinated by the diverse religious views on human embryonic stem cell research, both across traditions and within traditions. On May 7, 1999 the NBAC convened a meeting at Georgetown University to hear presentations on religious perspectives relating to human stem cell research. Eleven scholars in Roman Catholic, Jewish, Eastern Orthodox, Islamic, and Protestant traditions presented formal testimony that day, and two others made statements in the public comment period. Their statements, as well as later statements of other traditions (e.g., the Mormon tradition), reveal significantly different perspectives on the ethical acceptability of research on unimplanted human embryos. Even when similarly opposed to abortion, different religious positions may reach divergent moral conclusions about human embryonic stem cell research. Their different conclusions follow, in part, from different premises about the moral status of the early embryo existing outside a woman's womb.

Although Roman Catholicism officially opposes human embryonic stem cell research, some Roman Catholic moral theologians endorse it. A number of Jewish thinkers hold that the extracorporeal embryo, in the petri dish or cryopreserved, does not have standing in Jewish law and that it is justifiable to go forward with embryonic stem cell research. Protestants represent a wide range of views, as could be expected in view of the more than two hundred denominations in the United States that are identified as Protestant. Some Muslim thinkers also accept embryonic stem cell research.⁹

An interesting case in point is the Church of Jesus Christ of the Latter Day Saints (Mormons), which generally joins the Roman Catholic Church in strong opposition to abortion, but which has officially stated its neutrality on embryonic stem cell research, an area that it says "merits cautious scrutiny." The proclaimed potential to provide cures or treatments for many serious diseases needs careful and continuing study by conscientious, qualified investigators. As with any emerging new technology, there are concerns that must be addressed. Scientific and religious viewpoints both demand that strict moral and ethical guidelines be followed.¹⁰

The five Mormon senators support federal funding for embryonic stem cell research, without compromising their "pro-life" stance. The Mormon tradition does not rest its opposition to abortion on a declaration about when human life begins—it views abortion as similar to homicide. It holds that each person existed as a spirit child of God prior to receiving a physical body on earth. Thus, in what is a two-step process of creation spirit and flesh—the union of spirit and body marks the beginning of life on earth. In this context, stem cells may be comparable to the "dust of the earth," essential to human life but not human life itself.¹¹

In brief, no consensus exists among religious traditions—or secular moral traditions—about the moral status of the extracorporeal embryo. This diversity sets the context for an ethical assessment of public policy toward human embryonic stem cell research. An ethical public policy in our pluralistic society has to respect diverse fundamental beliefs. And yet it must not be held hostage to any single view of embryonic life.

IV. STEM CELL LINES DERIVED FROM ABORTED FETUSES

Another possible source of stem cells—human embryonic germ cells from aborted fetuses—has received scant attention recently.¹² However, precedent exists in U.S. policies for providing federal funds to support research on cell lines derived from aborted fetuses. This precedent appears in the framework developed for the use of cadaveric fetal tissue in transplantation research.¹³ This framework seeks to separate as much as possible a pregnant woman's decision to abort from her decision to donate fetal tissue for research. The rationale for this separation is to avoid any possibility, however slight, that the opportunity to donate fetal tissue in federally funded research could provide an additional incentive for a woman to have an abortion.

Several "ethical safeguards" were erected in order to prevent the use of fetal tissue in federally funded transplantation research from encouraging abortions. For example, these safeguards separate the consent process for abortion from the consent process for the donation of fetal tissue for research, and prohibit the donor of fetal tissue from designating the recipient of the transplant. These ethical guidelines, which appear to have been effective in human fetal tissue transplantation research, should now

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be extended to stem cell research as well, as the NBAC has recommended and the NIH has proposed.¹⁴ Even if at this juncture embryonic stem cells appear to be more promising than embryonic germ cells, derived from aborted fetuses, it would be appropriate to ensure that the current guidelines for the use of fetal tissue in federally funded research adequately cover research on embryonic germ cell lines. However, in the absence of a strongly felt need to use germ cells from aborted fetuses, the political reluctance to get embroiled in abortion wars may prevent such an action.

V. ANOTHER APPROACH TO PUBLIC POLICY—THE U.K. EXPERIENCE

The United Kingdom has responded quite differently than the United States to human embryonic stem cell research, including so-called "therapeutic cloning." Following the 1984 Warnock Committee report, the government implemented most Committee's British of that recommendations in the 1990 Human Fertilisation and Embryology Act, which, among other things, established the Human Fertilisation and Embryology Authority (HFEA).¹⁵ Over the last decade, the HFEA, currently chaired by Ruth Deech, has had authority over IVF, in policy and in practice. The HFEA also licenses and monitors all human embryo research in the United Kingdom, whatever the source of funding. In addition, it approves, in limited circumstances, the creation of embryos for research purposes. More than 53,000 embryos have been used in research, while 118 have been created specifically for research.¹⁶ In January 2001, following vigorous public debate, the British Parliament approved regulations to enlarge the range of acceptable goals for human embryo research and also to permit the creation of embryos for research by nuclear transfer ("therapeutic cloning").¹⁷

In the United Kingdom, then, years prior to the recent debate about stem cell research, several substantive and procedural standards were established for embryo research, including the creation of embryos for research. Furthermore, the public appears to have considerable confidence in that framework, based on a decade's experience. As a result, the acceptance of "therapeutic cloning" required only an extension of the existing framework, rather than the invention of a new one.

The U.K.'s strict regulation of reproductive technologies and authorization, but also tight control over, embryo research appears to have created a context for a positive response to the possibilities of human stem cell research.¹⁸ By contrast, in the United States, regulation of reproductive technologies and fertility clinics, which is under the control of the states, is, at best, limited and uneven, and the federal government has not allowed

the use of federal funds for embryo research (though, of course, privately funded research proceeds). As a result, the task of formulating public policy toward human embryonic stem cell research is much more challenging in the United States.

CONCLUSION

If President Bush's announced policy is ethically acceptable, as I believe it is, there is no cogent ethical reason for stopping where his policy stops-with the use of stem cell lines that were derived from embryos by August 9, 2001. Indeed, that temporal restriction is difficult to defend from an ethical standpoint. It is possible to use non-federal funds (or even, I would argue, federal funds) to derive stem cell lines from embryos within certain ethical requirements, and to provide federal funds for research on those lines without sanctioning or encouraging the destruction of embryos or the creation of so-called "extra" or "surplus" embryos in clinical IVF. I would support these other policy options-derivation with non-federal funds or with federal funds-on the grounds that they will probably enable important research to proceed more rapidly, and will not breach crucial ethical boundaries. In addition, it is ethically justifiable to provide federal funds for deriving and conducting research on stem cell lines developed from aborted fetuses, in accord with the guidelines and regulations already established for human fetal tissue transplantation research.

Whichever policies are adopted to enable important and promising stem cell research to go forward, within ethical limits, we will need a strong public body to review protocols for deriving stem cells from embryos (and from fetal tissue) and to monitor this research.¹⁹ Perhaps the Council on Bioethics, which President Bush has announced, could fulfill these functions, but it is not yet clear what its mandate and structure will be. If it does not fulfill these functions, some other public body will be needed, as the U.K. experience suggests. In the United Kingdom, the HFEA is statutorily established, and that might be a model for the United States, because we also need oversight of human embryo research in the private arena.

It is safe to assume that no policy currently under discussion will be the final one. We will need to revisit this research again and again as the science develops and as its ethical implications become clearer, particularly through a public body's on-going review and oversight. Thus, no policy will end the national conversation about how to balance, over time, the relevant ethical considerations. Our public dialogue needs to continue with as much rigor and imagination as possible. As we continue to reflect on the important issues raised by human embryonic stem cell research, we need a policy with greater flexibility than the one President Bush announced, but also with close review and oversight.

In a recent editorial in *Science*, ethicist LeRoy Walters stressed that "Governments and their advisors will need to be humble and flexible, but also decisive and courageous."²⁰ We must carefully scrutinize claims of scientific promise, being wary of unfounded optimism, but we must not neglect research that offers a significant prospect of major medical breakthroughs that may alleviate human suffering and reduce the number of premature deaths. As a society, we must provide clear and strong ethical guidelines, regulations, and safeguards for stem cell research, while avoiding unreasonably rigid rules that appear to be arbitrary and inconsistent.

References

1. 1 NAT'L BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH: REPORT AND RECOMMENDATIONS (1999) [hereinafter STEM CELL RESEARCH].

2. George W. Bush, Stem Cell Science and the Preservation of Life, N.Y. TIMES, Aug. 12, 2001, Sec. 4, at 13.

3. This is similar to the policy the NIH initially proposed in December 1999 and further refined in 2000.

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The Promise and Peril of Embryonic Stem Cell Research: A Call for Vigilant Oversight

Senator Bill Frist, M.D.*

Embryonic stem cell research raises issues that are fundamentally different from those affecting other areas of medical research. For the first time in history, we are faced with research that may profoundly affect the course of human life and disease by allowing us to more deeply understand and manipulate the basic building blocks of life itself. Although this research may produce powerful cures, it also holds great potential for unintended and even adverse outcomes.

Similar moral and ethical issues have challenged other areas of research, but the dilemmas posed by embryonic stem cell research are among the most challenging. It is an issue that cannot be left only to scientists, or ethicists, or patients, or religious leaders, as it is one that compels us to balance moral, ethical, scientific, and religious considerations. It is, therefore, vitally important that we are aware of the depth of the scientific, ethical, and moral issues involved.

In recent years, Congress has demonstrated a strong, bipartisan commitment to furthering biomedical research. But the unanimity surrounding medical research funding has been challenged by the issue of embryonic stem cell research—an issue that firmly confronts the ethical construct of biomedical research with the concepts of life and death, health and healing. In this piece, I provide an overview of the political and scientific history of the embryonic stem cell issue, evaluate the current political landscape, and discuss the future of this research.

I. HISTORY AND SCIENCE

On November 6, 1998, a team of researchers led by Dr. James Thomson at the University of Wisconsin published a paper outlining the successful isolation of pluripotent stem cells from human embryos, thus

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thrusting embryonic stem cell research to the forefront of debate.¹ As is well known by now, embryonic stem cells are derived from the inner cell mass of a blastocyst-stage (five to six days old) embryo. Although these inner cells have lost the ability to form supporting tissues, they retain the ability to develop into any cell type found in the body and are considered pluripotent. Over time, and if allowed, they may multiply and differentiate further, becoming committed to specific lineages. These pluripotent embryonic stem cells, when properly isolated and cultured, appear to contribute to all cell types found in the adult and seem to be capable of indefinite self-renewal.²

It is also now known that there exist relatively undifferentiated and self-renewing cells known as adult stem cells throughout the adult body—cells that help repair tissues harmed by injury, disease, or natural cell death. The most widely known and understood example of such a cell is the hematopoietic stem cell, found in bone marrow and responsible for the production of blood cells. Other promising cell types include neural stem cells and mesenchymal stem cells. Reports have also appeared touting the potential of stem cells from fat tissue, as well as those from umbilical cord blood.³

Until recently, adult stem cells were considered rare and inflexible, believed only to be able to form the cell types for the tissue in which they were found. Moreover, most adult stem cells have not grown well in culture and have remained difficult to obtain in significant quantities. However, recent news reports suggest that adult stem cells may have more plastic properties than previously believed, and the techniques for growing adult stem cells are being improved. For example, on January 23, 2002, New Scientist reported that researchers had discovered mulitpotent adult progenitor cells in adult bone marrow. Such cells appear capable of differentiating into all cell types and may avoid some of the difficulties associated with embryonic stem cells. Moreover, adult stem cells from human marrow have been expanded extensively in laboratories. While adult stem cells may not be capable of indefinite self-renewal, they do not also exhibit the tendency of embryonic stem cells to become malignant.⁴ Ultimately, there remain many challenges and uncertainties surrounding both adult and embryonic stem cells.

II. POTENTIAL APPLICATIONS OF EMBRYONIC AND ADULT STEM CELLS

Both human embryonic and adult stem cell research hold tremendous potential for a wide range of uses, including clinical applications of cellbased therapies for diabetes, Parkinson's disease, Alzheimer's disease, leukemia, spinal cord injuries, and a number of other diseases and injuries. This research may be useful in providing scientists with a better understanding of the human cellular growth and differentiation process, thus allowing researchers to seek out and attempt to treat or prevent the causes of birth defects, genetic abnormalities, and diseases. The research may also be useful in pharmaceutical development, allowing researchers to grow large numbers of various cell types in order to test drug effectiveness and toxicity.⁵

It is critical, however, that advocates not embellish the potential of either embryonic or adult stem cell research for medical therapies. This evolving science is still very young (the original Thomson discovery was published only three years ago). Further basic research must be conducted before we can hope to see clinical trials and possible treatments. In fact, with the exception of hematopoietic stem cells that have been used for many years in bone marrow transplantation, no other stem cells, neither embryonic nor adult, have yet demonstrated therapeutic applications.

Some of the challenges remaining for both avenues of research include: (1) learning the signals governing the differentiation of stem cells; (2) overcoming the challenge of immune rejection in cell transplantation; and (3) establishing consistent, effective methods to culture, isolate, and grow the cells in a timely manner that is consistent with good manufacturing processes.⁶ The bottom line is that treatments, if they will be discovered, are likely several years away. Yet, the hope that they will someday yield therapies for those suffering from disease is powerful.

III. THE IMPORTANCE OF FEDERALLY FUNDED RESEARCH

Our nation's unique combination of public and private funding for scientific research is the envy of the world. It attracts the best researchers and has led to an explosion of medical and scientific innovations that are producing new treatments and hope for patients suffering from a wide range of disease.⁷ Policymakers and the public are increasingly aware of the great potential of biomedical research, and this awareness has spawned an insatiable appetite for more and faster advances.

Because of this, Congress has worked during the past several years to double federal funding for the National Institutes of Health (NIH). In fact, the fiscal year 2003 budget proposed by President Bush completes this process, increasing NIH funding from \$13.6 billion in fiscal year 1998 to \$27.3 billion in fiscal year 2003. But to this point, many researchers have been discouraged from entering this new field of embryonic stem cell research because of the lack of federal funding. This is precisely why federal funding is so critical. It is clear that federal involvement in embryonic stem cell research will expedite scientific advancement by making the research available to scores of the nation's best and brightest investigators, and improve research by ensuring that adult stem cell and embryonic stem cell research are conducted along side each other.

Federal funding should also bring a much-needed level of ethical safeguards and federal oversight to the field. To date, embryonic stem cell research has taken place with no federal supervision or regulation. Reports of researchers deriving embryonic stem cell lines from human embryos created specifically for research have made this pressing need clear. The continually evolving interaction between this promising but uncharted new science with the ethical and moral considerations of life demands a strong, comprehensive, publicly accountable oversight structure. It demands a policy that is responsive on an ongoing basis to moral, ethical, and scientific considerations. It is, therefore, up to policymakers to ensure that this research is subject to the highest standards of public transparency and effective regulation.

IV. THE INTERPLAY OF SCIENCE, ETHICS, AND PUBLIC POLICY

As the desire for new therapies and treatments grows, we must recognize that science is not practiced in a vacuum. Moral and ethical considerations cannot be ignored. With the ever-increasing pace of progress have come new challenges of ethics and technologies that have, at times, threatened the ability of public policy to respond. But, I deeply believe that we, as legislators, have an obligation to do just that.

There are those who argue that "politics" should not impinge on scientific process. I disagree. It is the role of politics to ensure that taxpayer money is used in a manner that is responsive to public interest and is acceptable to society. It is the role of politics to ask the question posed by the *Washington Post* several years ago: "Is there a line that should not be crossed, even for scientific or other gain, and if so, where is it?"⁸ In fact, politics should and does have an important role in deciding what research is not only scientifically promising but also socially acceptable.

As a transplant surgeon, I have confronted many life-and-death decisions. I have performed hundreds of organ and tissue transplants and experienced the ethical dilemmas involved in end-of-life care. Having practiced in the early days of heart and lung transplantation, I have witnessed the powerful impact of medical progress on each of my patients. Moreover, I have seen firsthand the impact that medical and technological progress have had on reshaping legal and ethical criteria, as well as how ethics has shaped the practice of medicine.

As a surgeon, I frequently removed a heart from a brain-dead

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individual and placed that heart into another patient who would have otherwise died. That required a determination of when brain death occurred—a routine process today that was very controversial when it was first developed just three decades ago.

Historically, death was not particularly difficult to determine or define. Generally, all vital systems of the body—respiratory, neurological, and circulatory—would fail at the same time, and none of these functions could be prolonged without the maintenance of the others. However, technological advances in life support, particularly the development of ventilators, have made it possible to keep some bodily systems functioning long after others have ceased.

These technical advances opened up the possibility of organ transplants and also created a need for the development of a neurological standard for determining when death occurs. Only after death has been determined is it appropriate to consider organ donation. On this basis, there is now broad public support for organ donation. It must be remembered, however, that the cohesive interplay of science, ethics, and policy did not come easily.

A similar dilemma now confronts us in the field of embryonic stem cell research. The question is much like that faced in the early days of organ transplantation: Do we remove organs and tissue for transplantation and research from an individual who is brain dead, but whose other organs continue to live and function normally? The question today is whether to fund research using stem cells derived from blastocysts that could, if implanted, become a fetus, but that will otherwise be discarded. I believe the provision of funding for such research is the proper course, but only under the strictest of regulations to ensure a clear separation of the decisions to discard excess embryos, donate them for adoption, or donate them for research, in an approach consistent with the precedent of organ donation.

V. THE PRESIDENT'S DECISION

In the first half of 2001, the question of federal funding for embryonic stem cell research reached new heights of attention as pressure mounted for President Bush to determine whether to implement the NIH Guidelines on embryonic stem cell research, promulgated under the previous administration. With growing public interest, members of Congress were also forced to confront these issues. As the only physician in the U.S. Senate, I felt particularly compelled to study the issue and make my position clear. On July 18, I announced a comprehensive framework for the support of embryonic stem cell research.⁹ This position, based on

the following ten points, would allow stem cell research to move forward in a manner respectful of both the moral significance of human embryos and the potential of stem cell research to improve health: (1) a ban on the creation of embryos for research purposes; (2) the continuation of the present ban on federal funding of the derivation of embryonic stem cells; (3) a ban on all human cloning; (4) an increase in adult stem cell research funding; (5) funding for embryonic stem cell research only from blastocysts that would otherwise be discarded; (6) a rigorous informed consent process; (7) a limited number of stem cell lines; (8) a strong public research oversight system; (9) ongoing, independent scientific and ethical review; and (10) strengthened and harmonized fetal tissue research restrictions.

On August 9, 2001, President Bush announced a decision that may dramatically alter the course of biomedical research. After a lengthy process of thorough study, consultation, and reflection, the President decided to permit the NIH to fund research using embryonic stem cell lines already in existence on that date.¹⁰ His decision means that, for the first time, the nation's premier federally supported scientists will be able to perform research using embryonic stem cells. It means that, for the first time, this research will be conducted by a broad number of scientists-and not merely by those using private funds. Because the President's focus was on the use of existing cell lines, some of the protective criteria I detailed are not necessary-for example, as rigorous an informed consent process since the cell lines already exist. But the President's position expressly or implicitly endorses a number of my criteria, such as a ban on the creation of embryos for research, a ban on human cloning, and a ban on federal funding for the derivation of embryonic stem cells. These standards, in particular, and the President's decision ensure a strong and cohesive moral construct, in general, that will become even more critical as science and research in these areas progress.

As attention has focused on this research in the last year, a great deal has been learned about both adult and embryonic stem cells. During the President's deliberations, the NIH determined the existence of more than sixty embryonic stem cell lines worldwide—considerably more than previously thought.¹¹ There are presently more than seventy lines in the NIH registry. But this process has also reminded us how little is known about this science and has driven home the fact that there is still far to go.

In the wake of the President's decision, some have challenged the viability of all those cell lines. Others have argued that these cells lines are not enough to meet research needs.¹² Still others are disappointed that the President decided to allow the use of federal funds for research on any

embryonic stem cells.¹³

The President's decision means that embryonic stem cell research will expand dramatically. This research may open the door to therapies and cures beyond our imaginations. For the first time, federal funds will be used to better understand the earliest stages of human life, and the existence of a public embryonic stem cell registry should ensure that research and discoveries are shared broadly and rapidly.

We should commend the NIH for taking important steps to move this research forward through the establishment of a stem cell registry where researchers around the world, as well as the general public, can access information about embryonic stem cell lines available for research. This registry has already been important in bringing a new level of public transparency to the research and expanding our knowledge about the global state of the science. Because of the NIH's work in establishing the registry, we know the location of more than seventy embryonic stem cell lines that are currently available. Moreover, the registry includes information on how they were derived, what their basic characteristics are, and how to contact their owners.

The registry represents a commitment by the NIH and the President to facilitate scientists' access to embryonic stem cells. Moreover, the NIH has built upon the registry by negotiating a Memorandum of Understanding (MOU) with the Wisconsin Alumni Research Foundation, which holds patent rights to the cell lines developed by Thomson. The MOU enables the NIH and NIH-funded investigators to access these cell lines under minimal conditions.¹⁴ Hopefully, this agreement will serve as a model for such arrangements in the future.

But this research carries great moral as well as great medical danger, namely the potential to inflict harm. Because we have barely begun to understand its capacities, pioneers in the field must approach this research with the awe and respect it deserves. We must move forward with caution and restraint, remembering that it is untried, untested, and unproven. We must proceed within the context of a fully transparent, carefully regulated framework that ensures respect for the potential of this research and for the moral significance of the human embryo.¹⁵

Much of the public discussion and analysis of the President's decision has centered on whether his stipulations are sufficient for the success of this research. Issues such as autoimmune rejection and cell line diversity have been raised as potential obstacles.¹⁶ While the fact that existing cell lines have been cultured and grown on mouse feeder cells has concerned some, the Food and Drug Administration (FDA) has said that this is not a barrier to this research. In fact, there are presently several active Investigations for New Drugs for xenotransplantation products presently in clinical trials.¹⁷

While the concerns about the potential restraints of research limited to existing cell lines may one day prove valid, they will not prohibit the research from moving forward. Research knowledge will expand exponentially as we move beyond the relatively few cell lines isolated at the University of Wisconsin and begin to use the more than seventy lines available worldwide.¹⁸ Moreover, the NIH currently spends more than \$250 million per year on stem cell research—a figure that will continue to rise in the coming years as overall NIH funding continues to expand.¹⁹ Ultimately, far more research must be done before we know the answers to the concerns—but, it is now up to the researchers to move forward. Should there come a time that a real obstacle to the continuation and success of embryonic stem cell research emerges, Congress might look to alleviate such a situation in a manner consistent with the rigorous standards that I have outlined. But there is much work to be done before we will know whether this is necessary. This is, after all, a new and evolving science.

The President has also taken a crucial step towards the long-term success and viability of embryonic stem cell research by recognizing the need for continuing moral and ethical oversight of this and other pressing issues in the fields of bioethics and medical advancement. The new Council on Bioethics, to be led by Dr. Leon Kass of the University of Chicago, will play an integral role in monitoring and advising the nation about the moral and ethical considerations that may be raised by a wide range of scientific breakthroughs.

VI. THE FUTURE OF STEM CELL RESEARCH

One critical aspect of the embryonic stem cell framework that was perhaps overlooked, or afforded less attention, when I announced my position in July 2001, was cloning. It is imperative that federal legislation be enacted to ban all human cloning. There are three primary reasons I believe a ban is necessary. First, the technique by which cloning is done, somatic cell nuclear transfer, remains highly inefficient and risky to the embryo—with very high failure, death, and mutation rates. Second, allowing human cloning opens the door to the exploitation of women as egg donors by creating a market for already in-demand oocytes. This would lead to often poor minority women undergoing risky superovulation treatments because of the high financial incentives involved. Finally, there is broad agreement that the creation of embryos solely for research is unethical and should be prohibited.

In addition, science has progressed to the point that we know a human

cloning ban will not derail stem cell research. In 1998, when I authored one of the first pieces of federal legislation prohibiting cloning, concerns existed that a cloning prohibition would impede embryonic stem cell research. However, subsequent advances in our knowledge of the successful development of embryonic stem cell lines at the University of Wisconsin and the identification of more than seventy such existing cell lines to date have made clear that banning cloning will not materially curtail embryonic stem cell research. Science has advanced to the stage where we now know more definitively, not only that embryonic stem cell research will not be hindered, but also that such research can, and will, proceed aggressively without the use of human cloning.

We will have to wait several years to know whether embryonic stem cell research may yield practical therapies. In the meantime, we should move aggressively forward in implementing the President's policy and to examine its progress closely over the coming months and years. As the research moves forward, ongoing congressional and scientific oversight will be critical to reevaluating the progress and needs of this research. Just as important, ongoing discussion among scientists, policymakers, ethicists, religious leaders, and the American people will be critical to maintaining the proper balance between science and ethics and to ensuring the ultimate success of our biomedical research endeavors.

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A Scientific Rationale for Human Embryonic Stem Cell Research

Dan S. Kaufman, M.D., Ph.D.*

Stem cell biology has recently been at the forefront of a national discussion combining science, politics, and ethics. Few aspects of medicine and scientific research have been the subjects of a frenzy like that surrounding human embryonic stem (ES) cell research. Often lost amidst the opinions of pundits and op-ed writers in articles about research on human ES cells is: (1) the scientific basis of this research; and (2) the reasons why scientists and physicians are so interested in pursuing these studies. Quite simply, human ES cells are uniquely suited for research that uncovers the fundamental basis of human developmental biology. They might revolutionize areas of medicine such as transplantation medicine or gene therapy, and research on them will likely impact a wide variety of other fields. Indeed, in describing human ES cells, Harold Varmus, former director of the National Institutes of Health (NIH), said "[t]here is almost no realm of medicine that might not be touched by this innovation."¹ Under Varmus, the NIH released a report in which nineteen of its institutes each answered the question, "What would you hope to achieve from human pluripotent stem cell research?"² The health conditions potentially better understood or treated range from cancer to neurological diseases, to HIV and AIDS, to burns and trauma, to hearing and sight, and to drug abuse and mental illness. The scientific and medical impact of this research is almost endless.

The federal government, primarily through the NIH, provides the largest single source of funding for basic biological and medical research in the country. Whether or not the NIH is allowed to fund studies of human ES cells will determine how quickly scientific research on human ES cells will progress. On August 9, 2001, President George W. Bush gave his first nationally televised address since his inauguration.³ This speech

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addressed solely human ES cell research and the role the federal government should play in funding studies of these cells. In general, the President agreed that federal funding of research involving human ES cells would be permitted, but only on sixty or so human ES cell lines created prior to his speech. While this compromise did not fully satisfy either supporters or opponents of this research, it did set the stage to use federal dollars to move this research forward more rapidly.

I. STEM CELL BASICS

The most important basic concept about stem cells (and a point often not well understood) is that not all stem cells are the same. In general terms, a stem cell is defined as a cell that has two important characteristics: It can undergo self-renewal, and it can differentiate into two or more other cell types. Self-renewal refers to the property of these cells to divide without undergoing differentiation-as the cell divides and replicates to make more cells, each of these cells maintains an undifferentiated, multipotent, stem cell potential. However, in the proper environment or with the proper stimuli, a stem cell retains the ability to form more specialized cells, such as blood, muscle, liver, or skin cells. Two main categories of stem cells exist: adult stem cells and ES cells. Adult stem cells are those present within tissues of the body after birth. They are responsible for the continued growth of a single tissue or organ. For example, hepatic stem cells are in the liver, hematopoietic (blood) stem cells are in the bone marrow, and skin stem cells are in the basal layer of the epidermis. To maintain the integrity of a particular tissue or organ, these adult stem cells continually produce new cells to replace cells that are lost, diseased, or damaged. Hematopoietic stem cells (HSC) in bone marrow produce billions of blood cells daily. Some of these mature blood cells will survive months (red blood cells) or years (lymphocytes), while others only survive for a few hours (neutrophils). While HSCs make up no more than 0.1% of all bone marrow cells, their ability both to self-renew and to differentiate into a variety of cell types (like red blood cells, white blood cells, and platelets) enables the production of these billions of cells each day.⁴

In contrast to these adult stem cell populations, ES cells are not normally found in the body after birth. ES cells are derived from a cluster of cells called the inner cell mass (ICM) that exists for only a few hours at an early stage of mammalian development. The cells of the ICM normally differentiate into more specialized cells that form all the cells, tissues, and organs of the fetal and adult (post-natal) body. Under proper conditions, ICM cells can be placed in a tissue culture environment that allows them to be maintained as undifferentiated cells (now described as ES cells) that retain this potential to form any cell of the adult body. In this manner, ES cells were first derived from mouse blastocysts twenty years ago.⁵ Studies of these mouse ES cells have been instrumental to advances in mammalian developmental biology (e.g., providing an understanding of how specialized cells grow and develop from embryo to adult). However, the early stages of mouse development markedly differ from human development, so not all lessons learned from mouse ES cells may apply to human biology. It therefore became desirable to derive human ES cells. Many groups tried, but none succeeded until James Thomson and colleagues published a paper describing the derivation of human ES cells in 1998.⁶

Human ES cells have many of the same characteristics as mouse ES cells. Both can be maintained in culture for months or years without evidence of differentiation and without genetic (karyotypic) abnormalities, and both can be induced to differentiate into a variety of cells or tissues. Therefore, human ES cells are capable of both self-renewal and differentiation. However, researchers immediately noted differences between mouse and human ES cells. For example, the human ES cells grew more slowly and had a different morphology compared to mouse ES Moreover, the conditions required for maintenance cells. of undifferentiated growth are different between these cell types.⁷ These findings re-emphasize the fact that not all discoveries regarding mouse ES cells apply to humans. Whereas mouse models were previously regarded as optimal to learn about mammalian (and therefore human) biology, human ES cells must now be considered the "gold standard" to learn about human developmental biology.

II. BASIC SCIENCE AND HUMAN ES CELLS

The most obvious and important scientific reason to study human ES cells is to learn the basics of human developmental biology—how humans develop from a fertilized egg to an adult organism. As a researcher interested in blood development, I am interested in this system because it permits intricate studies of genes and proteins as blood cells develop from ES cells. Samples can be taken every day, every hour, or even every minute to understand in fine detail the changes that may occur as these cells grow and differentiate. The environment can also be altered to define what signals control whether an ES cell undergoes self-renewal to create more ES cells, or becomes stimulated to form blood or other cells of interest. There is no other method to examine closely these early developmental steps in a human system without using human ES cells. These cells promise

to open new vistas to show how humans develop from a single cell. Similar studies cannot be done using human adult stem cells, as these cells are already committed to a specific developmental lineage. Even if some of these adult stem cells are capable of changing their lineage fidelity (as discussed below), there is no way to determine how they reach that stage in the first place. That is, the early steps of development will remain a black box if research is confined to only adult stem cells.

Eventually, using human ES cells to understand better these earliest stages of human development will likely translate into clinical therapies and improved drug development. For example, it is impossible to test for harmful (teratogenic) effects of newly designed medications on pregnant women and the developing fetus. While these teratogenic effects can be tested in animals, the absence of adverse outcomes in a pregnant animal does not preclude the possibility that the medication would still be harmful to a developing human. This point was tragically demonstrated by the use of thalidomide by pregnant women in the 1950s, which resulted in limb deformities in children exposed to this drug in utero. Now, however, a potentially harmful drug might be added to an ES cell culture to see if it prevents normal growth of a few cell types of interest. For example, blood, neural, and muscle development can be monitored from ES cells in culture. These crucial lessons can be best learned from using ES cells as a culture model of embryonic growth. In the future, this model will likely prevent untoward teratogenic side effects of pharmacological therapies.

III. CLINICAL THERAPIES AND TRANSPLANTATION MEDICINE

Studies of human ES cells will teach us how cells develop and grow. This knowledge can then be applied to derive new ES cell-based therapies to treat a host of degenerative, malignant, and genetic diseases. The clinical field of hematopoietic cell transplantation (HCT) (commonly called bone marrow transplantation (BMT)) offers an excellent example of why human ES cell research is needed and the types of patients who will benefit from it. HCT is the only routine "stem cell therapy" currently performed in medicine. Thousands of patients a year undergo HCT typically to treat hematologic (blood) malignancies such as leukemia, lymphoma, or multiple myeloma. The greatest chance to cure these otherwise fatal diseases is by allogeneic HCT where HSCs from a healthy person are transplanted into the patient. When successful, these transplanted blood cells will grow in the new host as a means to eradicate malignant cells. Due to immunologic barriers, the donor and the host must be closely matched for tissue antigens (HLA molecules). Without this close matching, either the host will reject the donor cells or the

transplanted cells will cause overwhelming graft-versus-host disease that could be fatal to the patient. Optimal allogeneic HCT uses cells from an HLA-matched sibling of the patient; there is a 25% chance that any one sibling will be a perfect HLA match for the patient.⁸ If siblings do not match, then bone marrow donor registries are searched. While there are now over five million people listed worldwide in these donor registries, many racial and ethnic groups remain underrepresented.⁹ Studies have found that because it is so difficult to find an appropriate donor, only about one-third of patients who would benefit from an allogeneic donor actually receive a transplant.¹⁰ Patients without a suitable match may either undergo autologous HCT, where the patient's own hematopoietic stem cells are used, or receive additional chemotherapy without a transplant. While these treatments are often effective, the probability of curing the disease is typically less than with an allogeneic HCT." Despite more than twenty years of clinical experience with this type of adult stem cell therapy, obvious deficiencies exist and patients are dying who might otherwise live with new treatment options.

Human ES cells offer a novel source of cells to treat patients who do not have a suitable donor for an allogeneic HCT. Already, our research has demonstrated it is possible to derive hematopoietic cells from human ES cells.¹² Red blood cells, white blood cells, and megakaryocytes (platelets) can all be derived. The ability to transplant these ES cell-derived blood cells will be an important step to establishing these cells as a source of blood cells for patients without a donor. Even if these ES cell-derived blood cells are not directly transplanted into patients, the lessons learned by studying how blood cells grow and develop from human ES cells may provide insights that could be applied to help patients. For example, another potential source of cells for allogeneic HCT comes from umbilical cord blood. Although such cells come from the umbilical cord of a newborn baby, these cells are considered adult stem cells since they are committed to form only more blood cells. Cord blood cells seem to have unique properties when compared to other hematopoietic stem cells, and these cells could be successfully used for allogeneic HCT.¹³ However, only a limited number of cells can be isolated from an individual cord. While this number of cord blood cells is suitable for transplant into a child, there are often not enough of them for an effective transplant into an adult. Considerable research to find ways to expand the number of hematopoietic stem cells in a cord blood unit is underway. To date, however, researchers have not yet found the means to accomplish this ex vivo expansion routinely. Research on blood development from human ES cells may lead to scientific breakthroughs leading to more widespread use

of cord blood for clinical purposes. For example, these studies may define specific proteins and genes that are essential for growth of transplantable HSCs. We may then be able to identify a new protein, X, that leads to dramatic expansion of HSCs without differentiation. Addition of this protein, X, to cultures of cord blood may allow more successful ex vivo expansion of these cells. Eventually, this may permit more cord blood transplants and the ability to cure patients of devastating diseases that may otherwise be fatal.

IV. GENE THERAPY

Hundreds of diseases are caused by mutations or deficiencies of a single gene (a segment of DNA). Gene therapy refers to an area of science and medicine that attempts to treat disease by replacing abnormal DNA with normal DNA. Many vectors have been developed to insert new pieces of DNA into cells or tissues. For example, genetically engineered viruses can be inhaled or injected, leading to expression of a normal gene and potential improvement in the underlying disorder. Unfortunately, despite almost twenty years of studies and hundreds of clinical trials, this strategy has not been very effective, and few clinical successes have been published.

Cell-based therapies have been more successful at treating certain combined Children affected bv genetic disorders. severe immunodeficienies (SCID) lack functioning immune systems. These children are very susceptible to infections and will usually die at a young age without treatment. To date, the most effective means to treat SCID patients is with allogeneic HCT (as described above). This therapy replaces the abnormal blood cells with bone marrow-derived cells from an unaffected individual, leading to engraftment of a normal immune system and dramatically improved survival.¹⁴ Again, for reasons described above, many patients who would benefit from allogeneic HCT do not have a suitable donor. For some of these patients, gene therapy has successfully inserted the defective gene into cells of the immune system, leading to effective treatment,¹⁵ but this method remains difficult.

Human ES cell research could improve the treatment of such genetic diseases. Careful studies with mouse ES cells have shown that any cell in the body can be derived from undifferentiated ES cells.¹⁶ If we can learn how to derive specific cells and tissues from human ES cells, we could develop novel cell-based therapies. For example, blood cells could be grown for transplantation and treatment of immunodeficiencies. Hepatocytes (liver cells) could be derived to treat other enzyme deficiency diseases. Muscle cells, neurons, or any cell type in the body could be derived from human ES cells to treat better a variety of genetic or

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degenerative diseases. If needed, a gene could be directly inserted into human ES cells so that cells derived from these modified ES cells can sufficiently produce a protein that is lacking in a patient with a particular genetic abnormality. In this manner, the ES cells (or ES cell-derived cells or tissues) could become an optimal vector for gene replacement therapies.

Many barriers will have to be surmounted before the human ES cellbased therapies reach clinical practice. For example, methods to prevent immune-mediated rejection of transplanted foreign cells need to be established. However, the unique properties of human ES cells will spur scientists to overcome these difficulties.¹⁷

V. STEM CELL PLASTICITY

Some opponents of human ES cell research argue that human ES cell studies are unnecessary because adult stem cells are a suitable option for all proposed cell-based therapies. Several recent studies suggest that adult stem cells may have more versatility or plasticity than previously thought.¹⁸ Previous studies indicated that adult stem cells could differentiate into only a limited spectrum of tissue-specific cells.¹⁹ For example, bone marrow stem cells gave rise only to blood cells; neural stem cells gave rise only to neural and glial cells; and satellite cells in muscle cells gave rise only to muscle. Recent work suggests this may not be the case—adult stem cells may be more multipotent than previously believed. Such studies claim that bone marrow-derived cells develop into neurons and glial cells,²⁰ hepatocytes,²¹ and skeletal²² and cardiac muscle.²³ Muscle²⁴ and neural-derived²⁵ cells may produce blood, and skin-derived cells may produce neurons.²⁶ Under the right conditions, a single neural stem cell or bone marrow cell may differentiate into multiple tissue types.²⁷

While these experiments are intriguing, they do not obviate the need for human ES cell research. The scientific and clinical implications of these studies on adult stem cell plasticity remain unclear. While certain adult tissues may transdifferentiate into another cell type when placed in a suitable environment, other interpretations must be considered. For instance, it is possible that multipotent stem cells are found in minute amounts in multiple tissues. Placing these uncommitted cells in a particular environment may cue the observed results. Other possible interpretations also exist.²⁸

These studies on potential adult stem cell plasticity further highlight the need to make human ES cells a gold standard for stem cell-based research. We know that mouse ES cells can be grown in culture for years as undifferentiated cells, and yet retain their pluripotent capabilities.²⁹ In contrast, adult stem cells typically cannot be maintained for more than a few weeks in culture. Certain sources of these adult stem cells, like bone marrow or neural tissue, are difficult to obtain in suitable amounts, and the purity of these cell populations may be questionable. The ability to grow large numbers of well characterized human ES cells will best allow for studies to determine which specific genes and proteins regulate the development of particular tissues. As discussed above, the most important implication of the derivation of human ES cells is not the potential of these cells to be used for future therapeutic purposes. Rather, it is to understand better basic human developmental biology.

Basic scientific studies in fields such as genetics and developmental biology demonstrate the need to use multiple model systems. Yeast (Saccharomyces cerevisiae), worms (Caenorhabditis elegans), fruit flies (Drosophila melanogaster), fish (Danio rerio), and mice (Mus muscularis) each have particular strengths and weaknesses as investigational models to define the mechanisms by which cells and organisms grow and develop. Only by working on these alternative models have researchers obtained the basic knowledge that led to understanding normal human growth and development, eventually resulting in better therapies for human disease. Research on human ES cells will add another important piece to this puzzle. Eliminating our ability to use human ES cells might prevent a full understanding of the earliest stages of human development.

VI. THE BUSH DECISION AND THE FUTURE OF HUMAN ES CELL RESEARCH

President Bush's decision to allow federal funding of human ES cell research is a step in the right direction. While this announcement seemingly set an arbitrary date by which human ES cell lines needed to be derived in order to qualify for federal funding, the decision validates the role of the federal government in supporting and promoting advances in this exciting field. The NIH recently released a registry of sixty-seven human ES cell lines that are available to laboratories throughout the world.³⁰ With NIH funds available to expedite this research, progress will be made more rapidly than if only private funds were available to study these cells.

CONCLUSION

No one knows if these sixty or so human ES cell lines that qualify for federal funds will be enough to bring human ES cell-based therapies into clinical practice. If the goal of these studies is to derive transplantable cells to treat genetic, degenerative, or malignant diseases, then this limited number of cell lines is unlikely to be sufficient. However, if the goal is to use human ES cells to understand better the basics of human developmental biology, then this may be a reasonable number of cell lines for the near future. Scientific research does not always (or often) proceed in a straightforward, linear manner. Information must be gathered from multiple sources before conclusions can be reached. Human ES cells now provide a crucial model adding to the pool of information about human growth and development. Knowledge obtained from the basic study of these cells may likely be applied to other systems to improve clinical therapies directly or indirectly. There is no doubt that research on human ES cells will lead to progress in clinical medicine, but exactly how this research will impact future therapies for patients is difficult to predict.

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Stem Cell Research: Magical Promise v. Moral Peril

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It was not often that the word "magic" appeared in scientific literature until the advent of the stem cell. Now, this terminology seems to appear more and more often. If even half of the promises offered in the lay and professional literature come to pass regarding the magical nature of the stem cell, perhaps this hyperbole will be forgiven.

The potential for using stem cells to cure or ameliorate a host of genetic, metabolic, and degenerative conditions has been recognized only in the past few years, and this recognition has led to a major redirection of research efforts. In this relatively short time, a mixture of facts and fantasy has propelled the issue into the headlines; the surrounding fervor is fueled not only by the promises of magic, but also by the recognition that research and therapy with stem cells is not merely a scientific issue—it is also a profoundly moral issue.

While recognizing that stem cell research is also the subject of much scientific and political debate, this Case Study will focus primarily on the moral aspects. The nub of the moral issue is the source of the stem cells that are needed for research and therapy.

I. EMBRYONIC V. ADULT STEM CELLS

Human stem cells for research or therapy can be of embryonic, adult, or fetal origin. Embryonic stem (ES) cells can be derived from (1) embryos created specifically for the purpose of research; (2) "leftover" frozen embryos created for the purposes of in vitro fertilization; or (3) cell lines perpetuated in the lab, which were derived from either (1) or (2). Adult stem (AS) cells can be found in umbilical cord blood and placental tissue, as well as in many adult tissues, including bone marrow, fat, and brain. Fetal stem cells can be derived from primordial germ cells or the gonadal

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tissue of an aborted fetus.¹

In the stem cell debate, some individuals see no moral issue regarding the origin of the cells and are ready to proceed with whatever research shows promise. Most, however, recognize the moral issue and want to show due respect for the human embryo, but, on balance, are willing to compromise the moral issue in order to accomplish the promised magic. Others urge serious reflection on the moral issue and conclude that if there are two ways to approach the magic, one ethically troubling and another avoiding the moral issue, then we should take the moral high ground, using AS cells first and ES cells only if the former do not produce the desired results. Still others believe that ES cells should not be used even in the absence of morally acceptable alternatives.

Many researchers resist the urge to use AS cells, based upon the assertion that AS cells will not work as well as ES cells. Indeed, researchers initially believed that AS cells are more difficult to isolate and use. However, recent advances challenge this belief. After reporting on the successful isolation of AS cells from fat removed in liposuction, researcher Mark Hedrick stated, "This could take the air right out of the debate about embryonic stem cells. It makes it hard to argue that we should use embryonic stem cells."² Further, and of even greater significance, it was initially assumed that ES cells were pluripotent (i.e., could transform into any cell type) while AS cells were merely multipotent (i.e., could transform into a limited number of cell types). However, reports of human AS cells transformed into liver, nerve, bone, cartilage, fat, blood, heart, and other types of cells has prompted a rethinking of this assumption as well. In announcing the laboratory transformation of AS cells from bone marrow into brain cells, researcher Ira Black revealed to his doubting colleagues the feasibility of something they, just a few months earlier, had declared impossible. He concluded his announcement with the statement that "biological dogma has to be rethought."³

Not only have the previous assumptions been proven incorrect, but also, there are other reasons that AS cells may at least theoretically have advantages over ES cells. Using stem cells from the patient into whom the transformed cells will be subsequently implanted avoids the difficult issue of histo-incompatibility. Additionally, there is a greater propensity for ES cells to undergo uncontrolled transformation and growth, generating concern about malignant degeneration.

Fundamental to the issues at hand are conceptual questions about the nature of the cells we are dealing with. It is to these questions that we now turn.

II. THE BEGINNING AND THE END OF LIFE

Sperm and ova are human gametes. If left undisturbed, they will remain human gametes. However, once the twenty-three chromosomes from the sperm and the twenty-three from the ovum unite, they form a unique human being with the potential to pass through all of the stages of human growth and development—zygote, blastocyst, embryo, fetus, neonate, infant, child, adolescent, and adult.

Some argue that the zygote or blastocyst does not constitute a human being because each lacks the differentiated cells and tissues characteristic of human beings. Further, some argue that the blastocyst (or even the embryo or the fetus) is only a "potential human being." Potentiality has two possible meanings. First, it may mean that the item might evolve into the item mentioned, or it might possibly turn into something else. Second, potentiality may just mean that the projected evolution might or might not happen. The human blastocyst fails both of these tests of potentiality. Once it has been formed, the blastocyst cannot develop into a dog or a sheep; it is inherently and unchangeably human and, barring unforeseen intervention, will inevitably continue to develop into a human individual.

The cells resulting from the first two or three divisions of the zygote retain totipotency (i.e., if they are naturally or artificially separated, each can develop into identical copies of the others). Some argue that these cells are then not true human individuals. We would respond that they are indeed human individuals with the potential of becoming twins.

AS cells are human cells in the same way that blood cells, brain cells, or muscle cells are human. They are living cells with forty-six chromosomes. Thus, they are human cells. They reside within human tissue that in turn is part of a human individual. AS cells can be removed from a human individual without causing any harm to that individual. But the AS cell is not a human individual as is a zygote or blastocyst.

ES cells are also human cells in that they reside within human tissue. Prior to passing the point of potential twinning, each one is a potential human individual. After that point, they are human cells that make up the blastocyst—one stage of humanhood. In theory, removing one stem cell from a blastocyst would be morally comparable to removing stem cells from an adult's bone marrow. However, the reality is that the removal of that stem cell from the blastocyst necessarily destroys the blastocyst and thus the human individual. Herein lies the moral problem.

This essential nature of humanhood is inherent to the individual. It is not something that is imputed based on the location of the individual. Some maintain that implantation in the uterus is a more logical time to identify the individual than is fertilization. While it is clear that pregnancy begins with implantation, the human life has already been in existence for several days prior to the beginning of pregnancy. It is interesting and ironic that in the abortion debate, many argue that it is not a human until it is "out of the uterus," while in the stem cell debate many argue that it is not a human until it is "in the uterus." These arguments based on the individual's location are feeble attempts to deny the basic fact understood and accepted by scientists for many generations: Humanhood begins with the union of twenty-three chromosomes from the ovum with twenty-three chromosomes from the sperm.

Humanhood continues from fertilization until the death of the human individual. Certainly human cells and even human tissue can die while the human individual survives. Conversely, human cells and human tissue can sometimes survive for a while after the death of the individual. But there is a time when the human individual ceases to exist. Identification of this "time of death" continues to be the subject of scientific and philosophical debate. There can be little debate, however, that removal of cells from a blastocyst leads to the immediate death of the blastocyst, constituting the intentional destruction of that developing human individual.

III. THE ETHICS OF HUMAN SUBJECTS RESEARCH AND STEM CELLS

Having established that the human blastocyst or embryo is a human individual and thus should be accorded the same protections as other human beings, we now turn to the implications this has on the conduct of research. Human subjects research has been the focus of several international codes as well as extensive legislation in the United States. All of this legislation rests upon a common theme: Human beings are not commodities, and human beings must never be used as means to an end, but must always remain the end in themselves. Proposals to destroy embryos for research purposes clearly violate this most basic of ethical principles.

The first major international code of conduct in human subjects research is the Nuremberg Code, created in response to abuses of human subjects perpetrated by German doctors practicing under the Third Reich. The following quotes from the Code pertain to the topic at hand:

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the

disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be conducted where there is an *a priori* reason to believe that death and disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.⁴

A subsequent guide to human subjects research is the Declaration of Helsinki, published by the World Medical Association. The introduction to this set of research guidelines states, "considerations related to the wellbeing of the subject should take precedence over the interests of science and society."⁵ Amongst its Basic Principles, it states, "It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject."⁶ It further states, "Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others."⁷

In 1997, the European Union (EU) declared that, "The interests and welfare of the human being shall prevail over the sole interest of society and science."⁸ With regard to an individual who cannot consent to involvement in research, the EU stated that, "an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit."⁹

The 1979 Belmont Report published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research laid the foundation for research ethics in the United States. It said that research involving human subjects should be guided by the principles of beneficence, nonmaleficence, and justice.¹⁰ The current U.S. statute governing human subjects research, known as the Common Rule, defines "human subject" as "a living individual about whom an investigator [whether professional or student] conducting research obtains (1) data through intervention or interaction with the individual, or (2) indentifiable private information."¹¹ Specifically addressing research involving wards and children unable to give assent, the Common Rule states that research involving greater than minimal risk that will not yield direct benefit to the child, but will most likely produce generalizable knowledge about the child's disease or condition, requires that an institutional review board (IRB) find the risk to be only a minor increase over minimal risk and that the procedures be "reasonably commensurate" with those inherent in the child's condition.¹² Furthermore, if the research involves risk beyond this category, it is necessary that the research offers a reasonable opportunity to understand, prevent, or ameliorate a serious problem that affects the health and welfare of children.¹³

In addition to these regulations, the U.S. National Bioethics Advisory Commission (NBAC) declared that "the derivation of stem cells from embryos…is justifiable only if no less morally problematic alternatives are available for advancing the research."¹⁴

How then does ES cell research measure up to these standards of human research ethics? Animal models are still being developed and have not matured to the point of justifying the extraordinary claims for ES cell treatments. Thus, any claim that human embryos need to be destroyed now is unjustified. The data to date strongly suggest that the desired results are procurable using other means than ES cell research.¹⁵ The risks and burdens to the subject are clear, and proceeding with ES cell research clearly disregards the welfare and well-being of the subject for the sake of the "good of society." Further, these human embryos are not being exploited for the benefit of other embryos or very young children, but explicitly for adults, generally with adult-onset disorders. In summary, the proposed destruction of human embryos for research purposes is a clearly unethical violation of accepted principles, guidelines, and codes for human subjects research.

IV. RATIONALE FOR ES CELL RESEARCH

Research abuses perpetrated on post-natal subjects led to the development of these codes. However, it is eerily disturbing that arguments offered in the current debate about stem cell research employ the same rationales as those used by German physicians in their defense during the Nuremberg Trials. The following key points of comparison have been gleaned from a more complete enumeration by Michael Grodin.¹⁶

First, "[r]esearch is necessary in times of war and national emergency. Military and civilian survival may depend on the scientific and medical knowledge derived from human experimentation. Extreme circumstances demand extreme action."¹⁷ We are confronting a crisis of phenomenal proportions as millions are afflicted with diabetes, Parkinson's disease, Alzheimer's disease, and cancer. Indeed, the rhetoric of war is so prominent in the stem cell discussion that some researchers have claimed that the suffering of millions will be on the hands of those who do not permit and support this research.¹⁸ Second, "[t]he prisoners utilized for human experimentation were already condemned to death."¹⁹ Geneticist Jerome Lejeune has called these "leftover" frozen embryos prisoners in "the concentration can."²⁰ It has been claimed that these individuals should be used for research purposes since their fate is already doomed.

Third, "[e]xperimental subjects were selected by the military leaders of the prisoners themselves. An individual physician thus could not be held responsible for the selections."²¹ Similarly, the NBAC argued that the "leftover" embryos have been rejected by their parents and, thus, that the research community bears no responsibility for their deaths.²²

Fourth, "[s]ometimes it is necessary to tolerate a lesser evil, the killing of some, to achieve a greater good, the saving of many."²³

Finally, "[w]ithout human experimentation, there would be no way to advance the progress of science and medicine."²⁴ While this statement is indeed true, codes, guidelines, and regulations have been developed specifically for the purpose of bridling this research enthusiasm with ethical principles. One such principle is that human subjects research is never to result deliberately in the death of the subject, regardless of how much supposed good may result from the investigation.

Moreover, the Nuremberg tribunal, guided by the overarching principle that human beings are never to be treated as a means to an end, but must always be ends in themselves, soundly rejected the above arguments. It is sad and ironic that as the generation that bequeathed to us the Nuremberg Code is passing, we are discarding the wisdom it gained at such a high price. Using identical utilitarian and pragmatic reasoning, contemporary politicians, scientists, and the public at large are endorsing the commodification and destruction of members of our human family.

We are equating neither stem cell researchers with Nazi physicians, nor this issue with the Holocaust. We recognize that proponents of ES cell research are motivated by the desire to benefit individuals and society and not by racist eugenic policy. The focus of our argument is on human subjects research abuses. The historical record is clear that the logic and reasoning used to justify those abuses is identical to that being used today to justify the destruction of embryos. This should make us all pause and seriously reconsider these actions and proposals. Instances of human subjects abuse in America have resulted from the same flawed thinking. The Tuskegee syphilis study that devalued and commodified African-American men, the Willowbrook hepatitis study that commodified individuals with mental retardation, as well as others, claimed to focus on the greater good for the larger community. Yet, each suffered from the flaw of reducing its subjects to means to a larger end. We must also address the "stewardship" argument that is used to support the use of human embryos that are "leftovers" from in vitro fertilization. This argument maintains that the life will be lost anyway, as the embryo is destined to be thawed and discarded at the choice of the conceiving parents, and that we should allow the so-called redemption of this loss by using that life for research purposes. We must consider, though, that doing so only accepts and supports the erroneous and tragic approach of the infertility industry that perceives children as products and embryos as commodities. In reality, each embryo conceived is a child of the conceiving couple, and it is brazenly irresponsible to promote the idea that the parents have a right to discard as excess material the very child whom they deliberately conceived. A society that chooses to capitalize on this tragedy acts as opportunists, not as stewards.

If we are truly interested in the stewardship of the lives in question, we should promote responsible methods of assisting reproduction that do not result in the problem of having excess embryos. We should restrict fertilization to the number of embryos that the couple is willing to implant. Alternatively, we might insist that cryo-preservation occur at the pronuclear phase before fertilization is complete and a new, genetically unique human being has been conceived. This method has been demonstrated to be superior in terms of outcomes, yet the vast majority of fertility programs still cryo-preserve unimplanted embryos post-fertilization during the true embryonic phase. Further, when unimplanted embryos do exist, we should promote embryo donation and adoption.²⁵

Moreover, if we as a society actually believed in "stewardship," we would support research on prisoners condemned to death, and we would remove their transplantable organs either with or without consent. Yet, when recent Washington hearings discussed such practices taking place in other countries, the response, very appropriately, was one of horror and condemnation.²⁶ These events are not acceptable, because they cross a line that must not be crossed—they commodify human beings and reduce them to means to an end. Similarly, we cannot in good conscience demean and commodify another group of our human family, targeting them for destruction and harvesting them for a larger "social good."

V. REGULATION AND FUNDING OF STEM CELL RESEARCH

The moral issues raised by the use of stem cells for research or therapy has led to legal prohibition or restriction in many jurisdictions. In the United States, a lack of federal legislation governing this issue has resulted in intense political discussion of the provision of federal funds—a debate that strongly echoes the debate on federal funding for abortion services. While this Case Study will not review this political issue, the recent attempts at compromise deserve commentary.

President Clinton issued an executive order that allowed the use of federal funds for stem cell research, with the condition that federal dollars were not to be used to fund the actual retrieval of those stem cells. That compromise allowed the contemporaneous destruction of blastocysts using non-federal funds and the immediate transfer of those stem cells to federally funded research. President Bush proposed funding regulations that (1) encourage research with stem cells not of embryonic origin (free of moral implications) and (2) limit research on ES cells to the approximately sixty existing cell lines.

The primary issue raised by these compromises is that of moral complicity. Does the use of the product—or even information—gleaned from an immoral act implicate the current user in the moral wrong? An analogy often cited in an attempt to deny the concern of moral complicity is the transplantation of organs retrieved from a person who has been murdered. This does not implicate the surgeons or the recipient in the murder. Additionally, it redeems some good from that horrible act.

Debate about moral complicity has gone on without consensus regarding the use of data from immoral research, the use of illustrations made by the Nazi anatomist Eduard Pernkopf, the military use of information gained by Japanese biological warfare from 1932 to 1945, the use of vaccines developed using aborted fetal tissue, and other such atrocities. Some believe that the use of such information dishonors those who were immorally harmed or killed. Others claim redeeming value in salvaging some goodness from the immoral acts. The American Medical Association's Council on Ethical and Judicial Affairs concluded: "If ethically tainted data that have been validated by vigorous scientific analysis are the only data of that nature available, and such data are necessary to save lives, then the utilization of such data by physicians and editors may be appropriate."²⁷

The issue of separation of actions and intentions is determinative in discussions of moral complicity. In the Clinton compromise, the acts of retrieval of stem cells and research were separated, but the intentions were not. This disparity leads us to conclude that this compromise involved significant moral complicity of the researchers and of the author of the compromise.

The second part of the Bush compromise also raises the question of moral complicity. The acts that produced those sixty cell lines involved the immoral destruction of human blastocysts or embryos. The subsequent use of the perpetuated cell lines does not involve any inherent immorality, but it may involve moral complicity. Given that cell lines can be used in research and therapy for years, this issue is not a trivial one.

This sequence of events initially seems morally comparable to the use of organs retrieved from a murder victim. The murder is immoral, but the transplant is not; embryo destruction is immoral, but the research is not. But they are not the same. The difference is that the intention of the murderer is murder, not transplantation. The intention of those researchers who originally retrieve the stem cells is the use of those cells in research. To pick a point in time to distinguish allowable use from disallowed use is clearly arbitrary. Thus, current researchers may not be fully absolved from moral complicity, since they are using cell lines perpetuated after an immoral act for the actual purpose intended by the immoral act.

If President Bush had said, "I'm going to wait until there seems to be enough cell lines to declare a moratorium," that would have involved moral complicity. However, on the first opportunity he had to affect the direction of this research issue, he said, "While it is unethical to end life in medical research, it is ethical to benefit from research where life and death decisions have already been made."²⁸ His political compromise followed this reasoning.

As such, his compromise is not totally morally clean, but it is morally acceptable. It will never be justifiable, however, to say, "We don't have enough basic material. We need to allow another batch of cell lines through the gate." This would negate the arbitrary separation of allowed and disallowed research.

CONCLUSION

The retrieval of ES cells for use in research or therapy involves the immoral destruction of human individuals. Several codes of research ethics prohibit the use or destruction of human individuals for the benefit of others. The use of AS cells to pursue the magical promises of this research avoids this moral problem. The current compromise raises some issue of moral complicity, but it is morally acceptable as a one-time event.

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The Case Against Federal Funding of Human Embryonic Stem Cell Research

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The use of federal funds for human embryonic stem cell research is unwarranted. Beyond the substantial legal and ethical dilemmas inherent in such research, the scientific evidence shows that adult stem cells have vast biomedical potential to cure conditions such as diabetes, Parkinson's disease, heart disease, and other degenerative diseases. This biomedical potential is as great as, or greater than, the potential offered by human embryonic stem cell research. Simply stated, adult stem cell research is a preferable alternative for regenerative medicine and cell-based therapies because it does not pose the medical, legal, and ethical problems associated with human embryonic stem cell research.

In its September 1999 report on stem cell research, the National Bioethics Advisory Commission (NBAC) stated:

In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research....The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically. We recognize, however, that this is a matter that must be revisited continually as the science advances.¹ (emphasis added)

At that time there was only scant evidence for viable alternatives to embryonic stem (ES) cells for therapeutic use. A plethora of subsequent publications, however, provide ample evidence that non-embryonic stem cells (postnatal stem cells, including those from adult tissues, umbilical cord blood, and placenta, herein termed "adult stem cells") can fulfill all of our needs with regard to degenerative diseases. Indeed, the literature is now replete with citations showing the ability of adult stem cells to treat not only animal models of disease but also human diseases. In contrast,

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there is still only sparse and circumstantial evidence that ES cells can ever make good on any of the extravagant promises that have been made for them.

Several alleged shortcomings related to the biomedical potential of adult stem cells have been put forth. These allegations include that adult stem cells (1) have not been found in all tissues and are not pluripotent (i.e. cannot develop into cells and tissues of all three primary germ layers found early in development-ectoderm, mesoderm, and endoderm-from which all the cells of the body arise), and cannot form functional tissues; (2) are limited in number and difficult to isolate and grow in culture; (3) will be limited for use in treatments by risks of duplicating genetic error, and (4) will have limited applications for clinical treatments compared with ES cells. However, recent scientific developments indicate that these alleged shortcomings of adult stem cells either are illusory or can be overcome. In fact, an impressive volume of scientific literature attests to the fact that human adult stem cells-unlike ES cells-are currently being used successfully in humans to combat many of the very diseases that ES cells only prospectively promise to treat. Animal research indicates that more therapeutic applications of adult stem cells will follow.

Finally, the potential biomedical application of human ES cells faces risks unique to ES cells, including the tendency toward tumor formation, as well as gene expression instability. ES cells also face the very real potential of immune rejection, while use of a patient's own adult stem cells is free from this problem. Consequently, adult stem cells have several advantages over ES cells in their practical therapeutic application for tissue regeneration.

Thus, contrary to suggestions by supporters of human ES cell research, federal funding of such research is not a necessary or even a wise use of limited federal research dollars. Adult stem cell research is more promising, is demonstrably more successful at producing beneficial treatments actually used today, and does not present the significant problems and uncertainties (to say nothing of the ethical and legal problems) posed by human ES cell research.

I. ADULT STEM CELLS ARE PRESENT IN MANY (IF NOT ALL) TISSUES, ARE PLURIPOTENT, AND CAN FORM FUNCTIONAL TISSUES

Adult stem cells have not yet been found in every organ. However, they have been found in many tissues, including brain, muscle, retina, pancreas, bone marrow, peripheral blood, cornea, blood vessels, skin, liver, umbilical cord, placenta, and even fat.² Indeed, researchers have found that human adult neural stem cells can even be isolated from cadavers.³

More importantly, adult stem cells can regenerate healthy tissue and transform from one cell type into another. For example, plentiful stem cells from fat have been transformed into cartilage, muscle, and bone. Readily accessible bone marrow and blood stem cells have been transformed into muscle, heart, neural cells, liver, bone, cartilage, and other tissues. Adult neural stem cells have been reprogrammed to form skeletal muscle, blood, and all neural types. Stem cells from muscle can be coaxed into forming muscle, bone, and cartilage. And even adult stem cells from skin can form neurons, smooth muscle, and fat.⁴

Adult stem cells thus show pluripotency. In fact, published research indicates that adult neural and bone marrow stem cells may be able to generate all adult tissues.⁵ Clarke et al. suggest that "stem cells in different adult tissues may...have a developmental repertoire close to that of [embryonic stem] cells."⁶ The recent rapid pace of discovery, combined with the ability to form many, if not all, adult tissues, suggests that adult stem cells will ultimately be found in, or found to be capable of transforming into, every significant tissue type.

Contrary to the impression created by advocates of human ES cell research, the results for adult stem cells are far more promising than any obtained for ES cells, including the ability to form functional tissues in the body. The case for diverting scarce research dollars away from more promising avenues of research into human ES cell research in order to "cure" diabetes or Parkinson's disease is weak indeed.

II. ADULT STEM CELLS ARE PRESENT IN ADEQUATE SUPPLY AND CAN BE EASILY ISOLATED AND GROWN IN CULTURE

To be sure, adult stem cells are present in finite amounts throughout the body, but the supply of human adult stem cells immediately available is much larger than previously thought, and adult stem cell numbers can be expanded greatly in culture. Adult stem cells have the ability to rapidly and significantly proliferate so that sufficient amounts can be produced for clinical applications.⁷ Indeed, animal studies indicate that a single adult stem cell is sufficient to repopulate adult bone marrow, generate nerves, and participate in repair of a variety of tissues throughout the body.⁸ In fact, evidence now exists that human adult stem cells can be expanded indefinitely in culture.⁹

Arguments for federal funding of human ES cell research thus rely on an outdated understanding that markedly underestimates the number of adult stem cells present in an adult human and the efficiency with which those cells can be reproduced.

III. TREATMENTS USING ADULT STEM CELLS WILL NOT BE PROHIBITED BY RISKS OF DUPLICATING GENETIC ERROR

It has been asserted that adult stem cells are likely to be ineffective at combating genetic diseases because the patient's own stem cells would contain the same genetic error, making those cells inappropriate for transplantation. Evidence from clinical studies to date belies this assertion. The first successful human gene therapy used "remedied" adult stem cells to cure severe combined immunodeficiency syndrome (the "boy in the bubble" syndrome).¹⁰ In some cases the correction of the genetic defect may not be necessary to effect a cure with adult stem cells. For example, patients with systemic lupus have been treated with their own bone marrow stem cells that repaired organ damage previously considered permanent. This repair occurred without correcting any genetic defect present in the bone marrow cells.¹¹ Thus, a patient's genetic deficiency does not preclude the use of his or her own stem cells for therapeutic purposes. In fact, the use of one's own stem cells is medically preferable to use of ES cells, which carries with it a severe risk of host rejection and tumor formation.

ES cells are in fact the ones that will suffer from a risk of accumulating defects and DNA abnormalities. ES cells face the risk of mutation with every successive generation in culture; "[c]ells derived from stem cells that have replicated through many generations will have accumulated mutations and be susceptible to cancer or have decreased viability."¹² Therefore, an ES cell line grown in a lab for successive generations has an equal or greater chance of exhibiting undesirable characteristics compared to adult stem cells harvested from a patient for autologous (same-patient) transplantation.

Moreover, a recent study points to potentially significant problems with using ES cells for therapeutic treatments.¹³ For mice cloned from mouse ES cells, even apparently healthy animals had abnormalities that would be difficult to detect but could lead to disastrous disorders later in life. The abnormalities could be traced back to the ES cells themselves. The gene expression of the ES cells "was found to be extremely unstable," even in the culture dish.¹⁴ This instability suggests that using ES cells to treat health disorders may not work nearly as well as some have suggested, and would likely limit any use of ES cells in clinical treatments.

IV. ADULT STEM CELLS HAVE BEEN USED IN MANY CLINICAL TRIALS WITH GREAT SUCCESS AND HAVE BEEN USED SUCCESSFULLY IN TREATMENT OF NUMEROUS ANIMAL MODELS OF DISEASE

By contrast, adult stem cells have already been used in a variety of

clinical applications with considerable success. Such applications include treatments for various cancers,¹⁵ autoimmune diseases (such as multiple sclerosis, systemic lupus, and rheumatoid arthritis¹⁶), immunodeficiencies, anemias,¹⁷ stroke,¹⁸ and cartilage and bone diseases.¹⁹ Adult stem cells have also been used to regenerate corneas, restoring sight to previously blind patients,²⁰ and to treat cardiac damage.²¹ Simply stated, adult stem cells are already successful at treating a wide array of human diseases, presently providing results only promised by advocates of ES cell research.

The scientific record provides strong evidence for the conclusion that adult stem cells will be applied to treat a host of other human diseases and conditions, based on results in animal models. Adult stem cells have already been used successfully to treat various animal models of human disease, including nerve and spinal cord damage,²² Parkinson's disease,²³ heart damage,²⁴ muscular dystrophy,²⁵ diabetes,²⁶ stroke,²⁷ and liver disease.²⁸ Adult stem cells also appear to possess an ability to target sites of damaged tissue in the body, repairing damage and even attacking tumors.²⁹ As these studies move from animal models to clinical application, adult stem cells will be our best hope for fighting those diseases in the near term.

Contrary to the impression created by ES cell advocates, the biomedical potential of ES cells remains entirely speculative. Such cells have never been successfully used in clinical applications and have had lackluster success in combating animal models of disease. Thus, unlike adult stem cells, the biomedical potential of ES cells is purely speculative and a distant hope. Indeed, in contrast to human adult stem cells, human ES cells have not been successfully coaxed to make pure populations of most tissue types, even for animal models of disease.³⁰ Although ES cells may have great theoretical potential, they have been difficult to control in laboratories. The inability to manage ES cells successfully in the controlled atmosphere of a laboratory does not bode well for success as therapeutic treatments.

Even proponents of ES cell research have noted that ES cells are "tedious to grow," and that "simply keeping human ES cells alive can be a challenge."³¹ Not only is there difficulty in consistently coaxing human ES cells to differentiate into desired cell types, but also, there is the more fundamental problem of keeping ES cells alive. Significantly, ES cells also face a substantial risk of immune rejection.³² In stark contrast, the retransplantation of a patient's own stem cells carries with it no risk of immune rejection since the cells are the patient's own. No effective strategy has been developed to combat the problem of immune rejection of ES cells. Additionally, pluripotent ES cells have a tendency to form tumors.³³ University of Pennsylvania bioethicist Glenn McGee agrees,

noting recently: "The emerging truth in the lab is that pluripotent stem cells are hard to rein in. The potential that they would explode into a cancerous mass after a stem cell transplant might turn out to be the Pandora's box of stem cell research."³⁴

CONCLUSION

Compared with embryonic stem cells, adult stem cells have as great, if not greater, potential for biomedical application without the medical risks or the ethical controversy. The biomedical potential of adult stem cells is enormous. They are already used successfully to treat patients, and animal studies indicate that therapeutic treatments for numerous devastating human diseases are well within the vast therapeutic capabilities of adult stem cells. Studies strongly suggest that adult stem cells can transform into all significant tissue types. This transformative power of adult stem cells has caused one reviewer to remark that "[r]ecent studies have revealed that much of this remarkable developmental potential of embryonic stem cells is retained by small populations of cells within most tissues in the adult."35 One recent review proposes that "rather than referring to a discrete cellular entity, a stem cell most accurately refers to a biological function that can be induced in many distinct types of cells, even differentiated cells."³⁶ The authors liken the circulatory system to a "stem cell highway" in which adult stem cells may migrate from tissue to tissue, taking "on-ramps" and entering tissues to generate appropriate cell types in response to homing and growth signals ("billboards") as required, with all choices reversible.³⁷

Whereas adult stem cells continue to surpass expectations, ES cells have yet to live up to their billing as the new fountain of youth. ES cells are difficult to work with and carry with them significant risks that cast doubt upon their therapeutic viability. The shortcomings of ES cells, contrasted with the capabilities of adult stem cells, indicate that adult stem cells have many advantages as compared with ES cells in practical therapeutic applications.

There can be little doubt at this time that adult stem cells provide equal, if not greater, potential for biomedical application as compared with ES cells. Applying NBAC's own standard, the scientific record indicates that federal funding for human ES cell research is not justifiable. Indeed, less morally problematic alternatives for advancing the research are most definitely available, due to the stunning promise of adult stem cells.³⁸

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BOOK REVIEW

Compassion and Integrity in Medical Education

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Ward Ethics: Dilemmas for Medical Students and Doctors in Training. Edited by Thomasine K. Kushner and David C. Thomasma. Cambridge: Cambridge University Press, 2001. Pp. 284.

The process of medical training is grueling. Ward Ethics: Dilemmas for Medical Students and Doctors in Training (Ward Ethics) deals with the daily dilemmas faced by trainees as they struggle to respond to exhaustion, personal insecurities, the suffering of patients, and unethical behavior on the part of supervisors. Most of the cases in the book are not classic ethical dilemmas in the sense of there being uncertainty about the morality of a situation. The book is so filled with examples of unethical behavior that we wonder if anyone reading it would ever agree to see a doctor again. Instead, the dilemmas here focus on how the trainee should respond to unethical situations, and therefore, the issues are important ones.

The prototypical case in *Ward Ethics* is written from a medical student's perspective and reports on an episode where a patient is treated badly; the patient is either lied to, referred to with derogatory terminology, treated with disrespect, treated without adequate consent, or treated ineptly. The student responds with horror or sadness, is generally not in a position to provide any remedy, and wonders what to do. The prototypical commentary following these cases confirms the "wrongness" of the incident, sometimes explains why the behavior is wrong, and sometimes provides an explanation for why these situations exist.

Although one may be tempted to conclude that the behavior described in the book rarely occurs, consider one study's sobering finding

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that 40% of senior students did not believe that their teachers behaved as humanistic caregivers with patients or were good role models for the doctor-patient relationship.¹ That the medical trainees in *Ward Ethics* are more sensitive towards the patient than the senior physician is not surprising. Others have observed that students are naturally receptive to patients' emotions.² William Branch writes that "[s]tudents arrive on the wards idealistic. Because they are new, they may also feel like outsiders, and thus relate to some of the emotions that patients experience in the unfamiliar hospital environment."³

As students learn the technical skills needed to become physicians, they sometimes lose their receptivity towards patients. They are subjected to dehumanizing treatment such as sleep deprivation, verbal abuse, and humiliation.⁴ To avoid abuse, and perhaps to become less afraid, students strive to 'fit in' and model their behavior after their supervisors. Branch notes that "[t]his suppression of empathy not only prevents moral development but may even erode existing moral values. In addition to their own suppression, young doctors are assimilated into a ward culture that does not value empathy."⁵

What can be done, then, to cultivate the natural compassion and receptivity of medical students? First, students should be treated humanely. Providing students with protected time for reflection in small groups is one way to support students and demonstrate the value of self-awareness.⁶ However, any complete address of this situation would involve broad cultural change and would take a sustained effort on the part of any medical school or residency training program. Branch recommends establishing a climate of humanism in which students' natural compassion is nurtured through positive role modeling in clinical rotations.⁷ Although such an effort would take time, there is some evidence that these efforts can be successful.⁸

Ward Ethics attempts to address these issues and could be used as a text book for medical students. The book is divided into seven sections. Section One, entitled "Performing Procedures," deals with a complex array of issues such as the trainee's responsibilities for informing patients about their level of experience when performing procedures; performing physical exams on patients for practice or to demonstrate an interesting physical finding; performing procedures with inadequate supervision; practicing procedures on the newly dead; and observing senior physicians treat patients insensitively by disregarding a patient's pain, breaking a patient's confidentiality, or blaming a patient for their condition. Section Two entitled "Problems in Truth-Telling," covers errors of omission, such as nondisclosure of medical errors and withholding medical information from patients, and errors of commission, such as lying to supervisors.

Section Three, "Setting Boundaries," deals with sexual relationships with patients, empathy, and compassion. The chapter on compassion is particularly good. Our only criticisms are that this chapter falls under the "Setting Boundaries" section (perhaps implying that compassion is a boundary violation) and that the title, "The Limits of Compassion," may more appropriately be phrased as a question, "Are There Limits to Compassion?" since it seems more a topic for debate than a forgone conclusion. In fact, the importance of maintaining compassion is conveyed within each of the commentaries. For example, Guy Micco writes:

My answer to the question...—'are there limits to compassion?'—would seem to be 'no,' except for those limits imposed on us by time and other obligations. Yet we physicians have been brought up with the notion that too much 'feeling with' our patients is dangerous—for them and for us.⁹

Richard Martinez provides a thoughtful analysis of compassion as an emotional virtue. He writes:

Compassion, along with other professional virtues, is an important element in providing good patient care....I have rarely seen reason to discourage other health professionals in their cultivation of this quality. While learning to set limits on one's self and one's patients is an important component of professional development, remaining humanly connected to our patients and our work is vital.¹⁰

Section Four, entitled "Abuse and Mistreatment," deals with psychological abuse, physical abuse, and sexual abuse of trainees by their supervisors. We believe these issues should be confronted, but we were disappointed by the commentaries on sexual abuse of female students. Although neither of the two commentaries actually endorses sexual harassment, both seem resigned to its existence. Neither commentary expresses the outrage necessary to validate the emotional humiliation of women who have experienced sexual aggression or calls upon anyone to take responsibility for it. We wish the editors had included the opinion of someone who seemed more willing to take on the status quo.

In the first commentary, for example, Domeena Renshaw acknowledges that sexual harassment is unethical and inappropriate. She refers to the example of the surgeon who embarrasses a female medical student in the operating room with a group of snickering male surgeons by asking her suggestively, "[W]hich do you like best, 4 [inches] or 6 [inches]?" (referring to her preference for retractor length) as an example of a "soft" sexual innuendo.¹¹ Renshaw provides examples of clever retorts
(for example, "are you just a 1 inch?"), which imply that this is a better way to handle the situation than to report the perpetrator. Renshaw further cautions female students that reporting sexual harassment is often more trouble than it is worth. While we agree that students should be forewarned, Renshaw might also have more explicitly addressed the unfairness of a system in which a student risks further humiliation by reporting sexual abuse.

In the second commentary, Evert van Leeuwen also seems resigned to the existence of sexual harassment. He believes that medicine arouses erotic feelings that are necessarily repressed in the assumption of professional demeanor. Because of these repressed feelings, and because physicians rarely have training in sexology,¹² male physicians take these feelings out on their female colleagues. He writes, "[t]he more mental and rational they have to be in their encounter with patients, the more likely they may look for an escape in meeting young, vulnerable, not-yet-colleagues, like trainees."¹³ His focus on repressed sexuality as motivation for sexual harassment ignores the possibility that sexual harassment can also be motivated by violence and hostility towards women. The solution, according to van Leeuwen, is "that moral training of physicians should deal with persons of flesh and blood and not only with...politically correct, rational thinking brains."¹⁴ It is true that these issues should be addressed in the moral education of physicians. However, while we wait for that moral education of physicians to take effect, we would advocate for a more immediate solution by developing "no-tolerance" policies and punishing those who abuse women.

Section Five, "Argot, Jargon, and Questionable Humor: Assuming the Mantle at the Patient's Expense," focuses on mordant humor and derogatory patient references. Section Six, "Making Waves: Questioning Authority and the Status Quo," deals with issues related to the premature assumption of the title 'doctor,' duties to treat patients even at personal risk, observing senior physicians deliver poor medical care through neglect and ineptitude, treating patients with inadequate supervision, lying to patients, acting against authority, competing with peers, and conflicts of interest. This final chapter about conflicts of interest contains two wellwritten and persuasive commentaries by James Weber and Carson Strong focusing on gifts to physicians from the pharmaceutical industry.

One commentary in the "Duties to Treat" chapter involves a young female medical student who is called to the radiology department and asked to stand in the room with a patient while the patient (whom she has never seen before) has a CT scan. The medical student believes she is being used improperly (all of the other physicians and staff are standing in a different room to avoid exposure to radiation) and stumbles on a lie (pregnancy) that allows her to back out of the situation. We suppose that the inclusion of this case in the "Duties to Treat?" chapter is meant to be an example of when that duty does not exist, however it could equally have been included in the chapter on physical abuse. The first commentary appropriately identifies this as a case of extreme abuse, however, in the second commentary, Neal Cohen writes:

[N]o practitioner should lie to get out of a situation in which they feel uncomfortable. The medical student should expect that the risk will be defined and that appropriate protective measures offered. If they are not, the student should decline participation and, if necessary, discuss the concerns raised by the case with a supervisor. The student should be willing to describe their discomfort and discuss ways in which to ensure that the patient's care is optimized....¹⁵

Cohen's focus on the medical student's lie as a disturbing feature of the case seems misplaced and his advice that she should discuss her feelings with a supervisor overlooks the fact that it was her supervisor who asked her to expose herself to an unnecessary dose of radiation.

Section Seven is entitled "Perceiving Misconduct and Whistle-Blowing: Observing Peers or Superiors Commit an Act Deemed Unethical" and deals with substance abuse, rude behavior towards patients, nondisclosure of medical errors, the delivery of poor medical care by senior physicians, and misrepresenting research. The first chapter, which focuses on physician's abuse of drugs or alcohol, contains two thoughtful essays. In the first, Rosamond Rhodes observes:

Although a few instances of blatant inappropriate behavior are addressed, for the most part, misconduct is ignored. Although venues for employee grievances and hearing complaints...can now be found at many institutions, they are seldom used. In sum, medicine has failed to create an effective mechanism for addressing unethical behavior.... Whistle-blowers are ostracized, pressured to drop allegations, and threatened with counter allegations.... If faculty members are at such risk, the peril for a resident must be far greater, and everyone knows it.¹⁶

Rhodes then goes on to argue, "[t]o affect such a change in the status quo, the incentives for addressing problematic behavior have to be changed."¹⁷ Given the number and variety of egregious incidents described in this book, Rhodes' observations in this essay are relevant to almost every case in the book.

Ward Ethics draws its cases from around the world. One potential

benefit of this approach is that, for the most part, the experiences that medical trainees undergo seem to be largely the same in any country (e.g., observing disrespectful treatment of a patient and dealing with death for the first time) and there may be some value to the recognition of the universality of this experience. A potential risk of drawing on international examples is that trainees in the United States may find some of the international examples (e.g., performing surgeries without any supervision or dealing with the social consequences of British colonialism in India) unrealistic or dismiss them as irrelevant. For example, legal requirements, such as informed consent, and cultural expectations may differ from country to country.

The format of the book is a series of several cases followed by two or three commentaries. One general criticism about the book was its organization. The cases were not always grouped together for obvious reasons, making some of the commentaries a little diffuse. We also had some trouble understanding the organization of the chapters into sections. For example we did not think the chapter on blaming the patient or violating patient confidentiality should necessarily have been in the section entitled "Performing Procedures." We also did not think that the section entitled "Making Waves: Questioning Authority and the Status Quo" was different than the section on "Perceiving Misconduct and Whistle-Blowing."

Despite these criticisms, we believe that the book addresses important issues in thoughtful ways. While we were disappointed by the content of a few of the commentaries, many of the essays are interesting, and the cases themselves can serve nicely as foci for discussion in medical student curricula. We hope that medical education will continue to evolve such that the scenarios described in this book are confronted and the moral intuitions of medical students are nurtured.

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BOOK NOTES

Beyond a Western Bioethics: Voices from the Developing World. Edited by Angeles Tan Alora and Josephine M. Lumitao. Washington: Georgetown University Press, 2001. Pp. 176.

Physicians Alora and Lumitao join eight other contributors to provide a comprehensive exploration of bioethical issues outside the American and Western European model. Using the Philippines as a case study, they address how a developing country's economy, religion, and culture affect the bioethical landscape for doctors, patients, families, and the society as a whole. Contributors move from a general discussion of the moral vision informing health care decisions in the Philippines to an exploration of a wide range of specific cases: family planning, care of the elderly, organ transplants, death and dying, medical research, AIDS care, doctor-patient relationships, informed consent, and the allocation of scarce health care resources.

Caring for Patients at the End of Life: Facing an Uncertain Future Together. By Timothy E. Quill. New York: Oxford University Press, 2001. Pp. 264.

Dr. Quill uses his long experience in caring for severely ill patients to illustrate the challenges of, and potential for, end-of-life care. While examining the values underlying medical humanism, Quill provides practical guidance for clinicians, patients, and families about critical communication issues including delivering bad news, discussing palliative care, and exploring the wish to die. Through a case-based analysis, Quill explores some of the ethical and policy issues that arise in hospice work, including terminal sedation and physician-assisted suicide.

Claiming Power Over Life: Religion and Biotechnology Policy. Edited by Mark J. Hanson. Washington: Georgetown University Press, 2001. Pp. 192.

Developments in biotechnology, such as cloning and the decoding of the human genome, are generating questions and choices that traditionally have fallen within the realm of religion and philosophy: the definition of human life, human versus divine control of nature, the relationship between human and non-human life, and the intentional manipulation of the mechanisms of life and death. In this book, eight contributors challenge policymakers to recognize the value of religious views on biotechnology, and they discuss how best to integrate the wisdom of Christian and Jewish traditions into public policy debates.