INSIDE: MEDICAL RESEARCH, PRIVACY, INSURANCE, AND MORE

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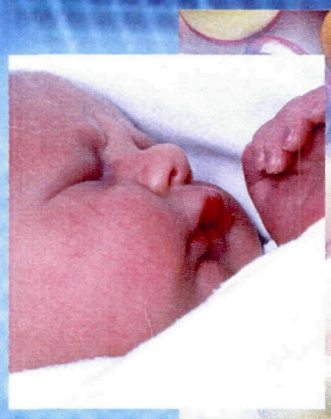

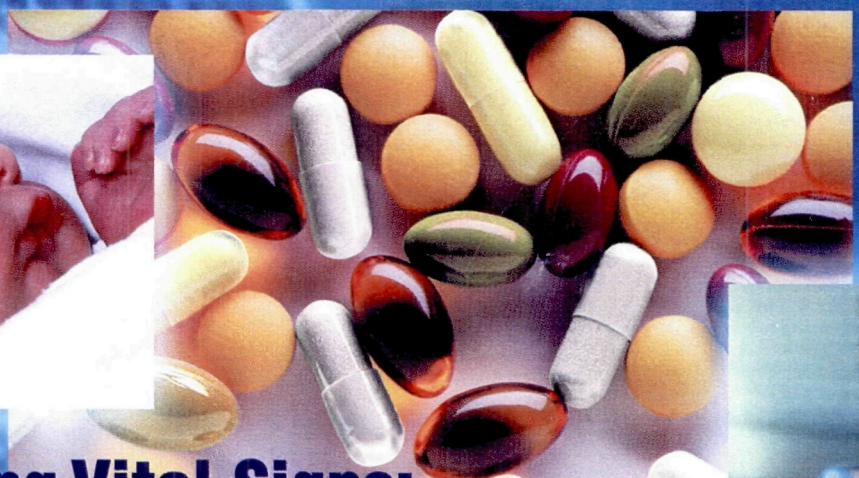

Checking Vital Signs: Medicine & The Law

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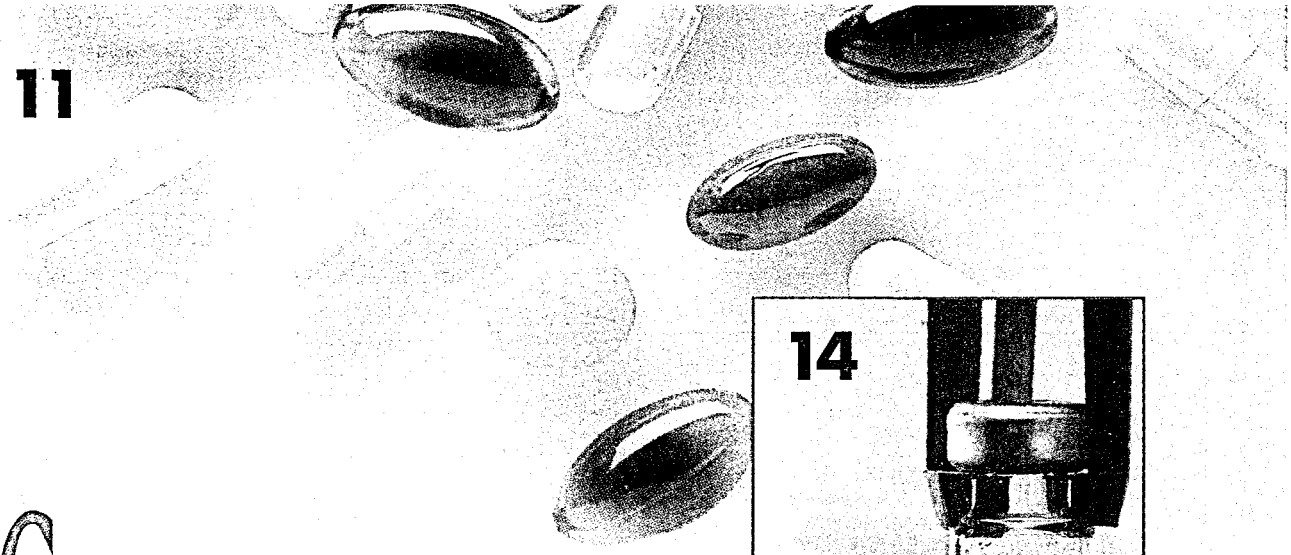

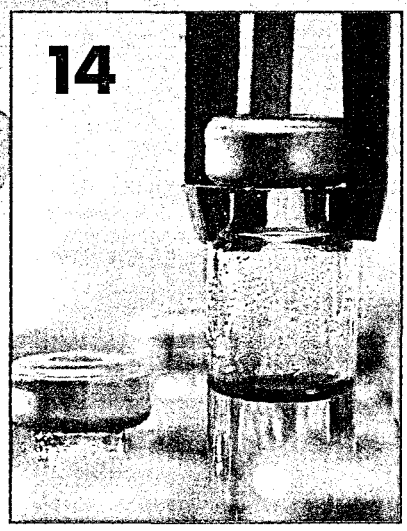

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"These are times that try men's [and women's] souls." Thus wrote Thomas Paine under the pseudonym Common Sense in 1776. While Thomas Paine was speaking about the American Revolution, these days of dealing with health care are just as trying for many. News reports, foundation and think tank studies, and even Congressional hearings are fodder for discussion as society studies and debates the role and magnitude of health care in America.

Health care costs continue to rise dramatically and there seems to be no easy explanation. In the 1980s and 1990s, providers and insurance companies evolved a system of health maintenance organizations (HMOs) and, subsequently, the preferred provider organization (PPO) in an effort to control costs. These systems were designed to provide a "gatekeeper" that would direct the consumer to the most efficient use of medical resources and prevent the "misappropriate" use of such resources, for example by discouraging the use of emergency rooms as primary care doctors and by limiting hospital stays.

The gatekeeper approach posed a philosophical hurdle for many consumers. Quality and access became the new buzzwords and consumers began demanding changes to the strict gatekeeper method to allow more freedom of choice.

The 21st century has brought a new list of issues. Managed care concerns still exist, but quality of care and enforcement are now hot topics. Controlling fraud and abuse is viewed as a new way of regulating costs. Along with the increasing regulation has come a call for patients' rights, including the right for consumers to sue the managed care organizations directly. Other new concerns for the consumer are privacy of personal medical information and confidentiality. Congress, state legislatures and regulatory bodies have rushed to address these concerns, resulting in a new wave of laws, as well as new regulations to implement these laws.

In this edition of *Delaware Lawyer* we focus on some of these "new" issues that are affecting the health care system today. Mike Rich takes on the very complicated topic of privacy. Karen Lines addresses the concerns facing the pharmaceutical industry as it seeks to comply with federal laws and regulations. Congressman Michael Castle provides an update on the issue of biomedical research and the need for funding of such work. Dr. Stephen Lawless, Chief Knowledge Officer for Nemours, and his co-authors discuss children's health in Delaware, while Susan Paikin and her co-author provide an overview of the new relationship between child support and medical care.

These five articles touch on many issues that are overlooked in the popular press. I hope that these articles will give you an idea of the many challenges that must be addressed in the brave new world of health care.

Sandra K. Battaglia

MICHAEL N. CASTLE is currently serving his fifth term as Delaware's sole Member in the United States House of Representatives. He began his legal and political career over 35 years ago and was a former Deputy Attorney General, state legislator, Lieutenant Governor and two-term Governor of Delaware. Mike Castle has played a key role in enacting many important laws which have improved the lives of Delawareans and all Americans. For instance, he has been instrumental in helping to write and pass Welfare Reform, the Balanced Budget Act, Child Nutrition Programs, Education Flexibility, K-12 Education Reform and Campaign Finance Reform. Representative Castle has always been active in the Delaware Bar Association and was the guest speaker at the 2002 Law Day Luncheon.

STEPHEN T. LAWLESS, M.D., originally came to Nemours in 1990 and is Board Certified in both Pediatrics and Pediatric Critical Care. He received his MBA from Wharton in 1996. He was appointed Chief Knowledge Officer for Nemours in 2002. Dr. Lawless concurrently is the Medical Liaison for Quality for the Alfred I. duPont Hospital for Children and is an Associate Professor of Pediatrics at Thomas Jefferson University. Dr. Lawless still maintains a clinical practice as one of the staff Pediatric Intensive Care Unit Physicians at the Alfred I. duPont Hospital for Children. Dr. Lawless's co-authors, MARGARET McSOLEY COUPE and DANA L. FERRELL, serve as Executive Associate to the President and Director of Government Relations for Nemours, respectively.

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company, in South San Francisco, California. Currently, much of her focus has been on enhancing Genentech's Commercial Compliance Program and addressing compliance issues relating to the HIPAA Privacy Regulation. She began her legal career in private practice in Wilmington, Delaware, with Prickett, Jones and Elliott and with Potter Anderson & Corroon.

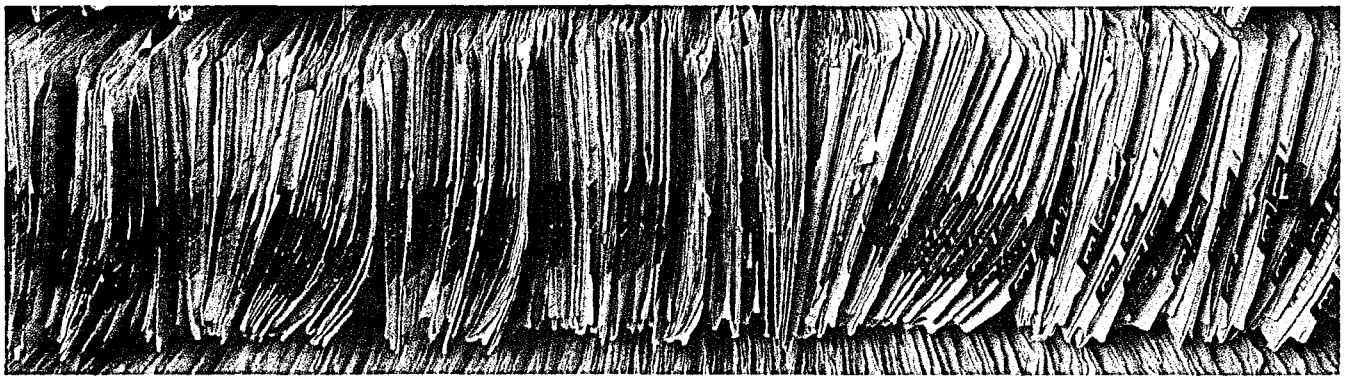
MICHAEL J. RICH presently serves as the Deputy Attorney General for the Department of Insurance where he is involved with many health care issues including privacy policy and acquisitions and mergers. Prior to joining the Department of Insurance he served for six years as the State Solicitor and spent over 20 years in the private practice of law. He also is a former President of the Delaware Bar Association and former Chair of the Delaware Board of Bar Examiners and currently is a director of the Delaware Bar Foundation. He has contributed several articles to the *Delaware Lawyer.*

SUSAN F. PAIKIN is a Senior Associate with the Center for the Support of Families, a Maryland-based consulting firm that works with state and federal agencies on developing and implementing policy regarding children and family issues. In this capacity she assisted the federal Medical Child Support Working Group in the design and editing of its report. She also served as an official observer on the National Conference of Commissioners on Uniform State Laws that drafted UIFSA and UPA (2000). Ms. Paikin is a member of the *Delaware Lawyer* Board of Editors. Ms. Paikin's co-author DANA K. McKENZIE is an attorney with vast experience in the family laws arena in both the private and public sectors. Ms. McKenzie currently serves as Manager of the Policy and Planning Section of the Minnesota Department of Human Services, Child Support Enforcement Division. ◆

FEATURE

Michael J. Rich

HEALTH INFORMATION AND PRIVACY INTERESTS IN THE 21ST CENTURY



The protection of individual privacy generally, and personal health information specifically, has been an important and recurrent issue in the history of American jurisprudence. The protection of personal health information and medical privacy developed from the common law protection of the physician-patient relationship. As medical science and technology became more sophisticated, the states passed new laws to assure the continued protection of personal health information and personal medical privacy. There are two aspects of modern America that have significantly changed the manner in which medical information is maintained and shared. The first is the technological changes that have dramatically altered the medical profession's ability to diagnose and treat patients. The second is the mergers or acquisitions of disparate but related businesses that share common databases of information for commercial purposes. Foremost among those business combinations are the companies with subsidiaries that are engaged in banking, mortgage lending, credit issuance, securities brokerage and insurance and which have the ability to obtain and share vast quantities of personal financial and health information.

This article will discuss the relationship among the competing interests for health information including the patient, the medical providers, insurers and the government and how developments in the law have affected those relationships and the balance among them. This article will also explore how health information is protected under Delaware law and how changes in federal law, primarily the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Gramm Leach Bliley Act ("GLBA"), have impacted personal rights to the privacy of personal health information.

The most important aspect of medical privacy is that which involves the patient and the treating physician. It is direct, personal and touches every person in the country. One step removed is the use of medical information for research or clinical study. Historically, the treatment of disease and development of preventative care techniques have come about because medical researchers have undertaken clinical studies or reviewed actual cases in order to apply that knowledge and learning to the care of well individuals. Whether by actual observation in teaching hospitals, through peer review, conducting drug trials, or through clinical or university research, information has been collected, stored and shared for centuries as part of the development and perfection of medical techniques.

For most of the twentieth century, the personal privacy issues were focused mostly on information sharing between the patient, doctor and related medical providers. Building on the direct privacy relationship between doctor and patient, the medical profession recognized that, even in the less direct areas of research, the patient had certain privacy rights in his or her medical information and treatment. As a result, the practice developed of obtaining consents for the retention, use and sharing of personal health information for research purposes. During the latter half of the twentieth century, with the proliferation of medical insurance and medical coverage plans, consents were expanded to include the sharing of information with the insurers providing reimbursement for medical care and services, as well as the related facilities, including hospitals and medical groups. Politically related legal-medical issues spawned new legislation as society confronted issues such as the sharing of genetic information. The government interest in public health issues, especially communicable diseases such as tuberculosis, plague, typhus, and AIDS as well as other sexually transmitted diseases raised issues relating to the extent to which personal health information could be shared and

stored for public health and protection purposes without patient consent. Human clinical trials in the drug approval process required the storage, comparison and publication of significant amounts of medical data based on patient consent. It is axiomatic that as the ability to store, compare and transmit information has increased, the private and governmental interest in the protection of personal health information has likewise proportionately increased.

Delaware Laws Protecting Personal Health Information

Delaware has no overriding central statute relating to the privacy of personal health information. Delaware does have a number of laws and regulations that are issue specific. The foremost of these laws dealing with the comprehensive nature of storing and sharing personal health information is the Delaware Health Information Network.[1] The General Assembly intended the Health Information Network to be a public instrumentality, under the direction and control of the Delaware Health Care Commission, to promote facilities for the public and private use of health care information in the State with the express purpose that the Network "ensure the privacy of patient health care information."[2] Specifically, the law requires that patient-specific health information be disclosed only in accordance with the patient's consent, that the Network's records are exempt from the Freedom of Information Act or court subpoena, and that violations of the statute's protocols be prosecuted under applicable state or federal criminal laws.[3]

In addition to the Network, Delaware also required the establishment of a health information database to assist the health care system in advancing the general well being of the population by better directing and improving the availability of health care services.[4] In establishing this database the State intended to assure the efficient use of health care resources by having an appropriate repository for health information necessary to evaluate community needs and costs of service. The collection of such information for the allocation of health care resources must be done without compromising patient confidentiality. The law presumes that the information contained in the database shall be available to health care purchasers, health care insurers and health care providers, as well as the general public.

Delaware's laws relating to managed care organizations require that such organizations assure the privacy of their subscribers' personal health information.[5] Delaware has a specific confidentiality statute with respect to HIV testing, which prohibits the identification or the ability to compel the identification of any person seeking an HIV test.[6] A person's genetic information cannot be collected or obtained without first obtaining the person's informed consent unless there is a criminal, juvenile, paternity or other appropriate judicial proceeding, or appropriately protected anonymous research. Nor can a person disclose or be compelled to disclose (including by subpoena) the identity of an individual upon whom genetic testing has been performed unless authorized for purposes which mirror the exemptions for obtaining consent for genetic information.[7]

Another issue, which will be discussed in more detail subsequently, is the interest of the medical profession in sharing health information for purposes of research and treatment. For a practicing physician, especially a physician on the surgical or medical staff of a hospital, the ability to exchange information, including personal health information concerning patients, is crucial to the physician's continuing education and credentialing requirements that the members of the medical profession have to maintain. Delaware provides that the peer review boards of the Board of Medical Practice, the Medical Society of Delaware or committees appointed by certified health maintenance organizations, hospitals, osteopathic medical societies and the like, shall be immune from any claim, suit, liability, damages or other recourse from any actual proceeding undertaken in good faith by those peer review boards. The proceedings of any of those peer review boards or organizations are immune from other civil or criminal legal process. No person in attendance at such meetings can be compelled to provide testimony relating to the proceedings of any such board or committee. The only exception is that the Board of Medical Practice may use information obtained by a peer review board as part of a disciplinary proceeding against a physician charged with a violation of the Medical Practices Act.[8]

In addition to the laws already discussed, hospital and residential centers that admit persons for treatment of mental illness must release their records to the patient.[9] Nursing home patients have a right to inspect that facility's records pertaining to a person's care, which must be produced within twenty-four hours of a written or oral request.[10] Dental plans are restricted from divulging information relating to an enrollee's personal health information.[11]

Delaware Rule of Evidence 503 governs the extent of the physician- and psychotherapist-patient privilege. A communication between a patient and a physician is confidential if it is intended only for the use of the physician and others participating in the care and treatment of the patient under the direction of the physician and not communicated to persons outside that circle, including members of the patient's family. The authorized exceptions include communications relevant to a proceeding to hospitalize a patient for mental illness, court ordered examinations, the appointment of a guardian in child abuse cases and where the issue of a person's health is an element in an ongoing proceeding. In addition to the physician and psychotherapist privilege, Delaware law provides protection for the disclosure of mental health information to associated professionals, particularly licensed clinical social workers.[12]

The privilege applies to administrative cases as well. In an industrial accident case, the Greenwood Trust Company sought a writ of prohibition to forestall the discovery of personnel and medical records of its employees in workers' compensation cases against Greenwood resulting from allegations of "sick building" syndrome. The Industrial Accident Board approved limited discovery of personal health information for the purpose of compiling evidence in the pending case. The Board allowed the claimant's medical expert to collect the information but ordered the expert to protect the confidentiality of the records and not to release the names of any individuals whose records were reviewed. The IAB did not require, but did permit, the employer to redact identifying information. In deciding the writ, The Superior Court recognized that the

board had an obligation to protect medically sensitive and private information and could make rules consistent with medical privacy to carry out its statutory mandate. The court concluded that while it might be burdensome and expensive for the company to produce the records of its employees, it had overstated the burden that was placed upon the company and that the board had acted appropriately to protect the medically sensitive information and the privacy of the individuals involved. The writ was denied and the order of discovery was upheld.[13]

The Gramm Leach Bliley Act ("GLBA")

The protection of personal, financial and health-related information has been an area of congressional and federal agency concern over the last several years culminating in two specific federal enactments that significantly govern the privacy of consumer, financial and health-related information through GLBA and HIPAA.

The last two decades of the twentieth century saw the merger and acquisition of separate but related companies into large interlocking companies where back-office operations and economies of scale could generate better profits through the common storing and sharing of related information. As a result, mergers like the one between Travelers and Citicorp resulted in single entities providing banking, brokerage, property and casualty insurance, life and annuity products and health insurance. Congress was concerned that a company taking a mortgage application could transfer health or financial information to a credit card or insurance company irrespective of the affiliation between the companies. A health or automobile insurance company could share or transfer health or claims information to a credit or banking company. GLBA, signed into law by President Clinton on November 12, 1999,[14] was a comprehensive legislative act that modified or created new privacy requirements in the areas of banking, insurance and financial institution related law. GLBA prohibits disclosure or exchange of health and financial information among unrelated companies without disclosure to and permission from the consumer within a framework that allows affiliated companies to share information by mere disclosure to the consumer.

by the National Association of Insurance Commissioners ("NAIC"), and adopted by over thirty-four states by July 1, 2001, provided protection for consumers with respect to the privacy of their health and financial information held by these commercial financial institutions.

Under GLBA, non-public personal health information is any information that identifies a person in some way and includes information about that person's health, including the past and present physical and mental health and details of health care and payments for health care. It includes information with respect to chronic or acute conditions, mental health, the types of medication a person takes and the treatments one receives. An insurer must obtain a customer's consent prior to disclosing non-public personal health information to any other party except for items relating to claims management, underwriting and legal investigation or defense, including regulatory compliance or fraud investigation. Under GLBA, the company must provide a disclosure to the customer describing the terms under which customer information will or won't be shared or exchanged with any other person, firm or entity. The disclosure must inform the customer that personal health information won't be shared or disclosed except as permitted by law unless the customer "opts in" and allows such sharing. Conversely, financial information is discloseable unless the customer "opts out" to prohibit disclosure.

Delaware is one of sixteen states that adopted the NAIC model privacy regulation without the health information provisions.[15] One of the reasons Del-

One protective aspect of the GLBA privacy regulation is that the insurers and financial institutions subject to that regulation are required to give annual privacy notices updates to their customers with respect to the disclosure of personal financial or health information.

The Health Insurance Portability and Accountability Act of 1996

The most comprehensive federal foray into the issue of personal health information protection is the Standards for Privacy of Individually Identifiable Health Information ("the rule") promulgated by HSS under HIPAA.[16] The rule took effect on April 14, 2001. All of the health providers covered by the rule must comply with these requirements no later than April 2003. The rule applies to virtually every health provider and insurer in the country except for workers' compensation insurers, most automobile and property liability insurers, health coverage benefits policies, nursing home fixed indemnity policies and certain limited benefits covered policies. The purpose of the rule is to establish national standards for the protection of individuals' medical records and other personal health information. The salient features of the rule are that it:

- Gives patients more control over their health information.
- Establishes standards for the use and release of health records.
- Establishes safeguards which providers and insurers must. achieve to protect such information.
- Establishes civil and criminal penalties for violation of the rule.

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Under the rule, every provider will have to establish a procedure for the safeguarding of information including the assignment of a specific person to be responsible for the protection of personal medical health information in each office where such information is collected and stored. There is substantial flexibility for smaller offices to establish tailored plans to fit the particular business practices of that office. Larger practices and insurance companies will need a full-time dedicated person or department responsible for information privacy and security. The more an office will need to share the information it holds with others, the stricter the standards for the protection and security to which that office will be held.

Another significant aspect of the rule will be a requirement for a patient's consent for the routine use and disclosure of health records for non-personal uses. Therefore, there will be more limitations than in the past with respect to the use of medical health information for academic research without obtaining the patient's consent. Nevertheless, the rule does recognize the government's significant concerns about public health issues and takes into account the fact that information may be disclosed to appropriate investigative or health officials where issues of public health may be concerned.

The federal Office of Civil Rights will be responsible for enforcing the civil and criminal penalties for violations of the rule. For non-criminal violations of the rule, including erroneous disclosures, there are civil monetary penalties of $100 per violation and up to $25,000 per year per standard. For

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The act required financial regulatory agencies like the Office of the Controller of the Currency, Federal Trade Commission and the Federal Reserve Board to promulgate or amend regulations relating to the security and privacy of customer information. To avoid federal preemption of states' traditional regulatory role vis-a-vis insurance companies and companies selling insurance products, GLBA required that at least seventy-five percent of the states adopt uniform and consistent regulations relating to the protection of consumers' financial and health information held by insurance companies, and their affiliated or related companies, prior to July 1, 2001. As a result, the Model Regulation adopted by the National Association of Insurance Commissioners ("NAIC"), and adopted by over thirty-four states by July 1, 2001, provided protection for consumers with respect to the privacy of their health and financial information held by these commercial financial institutions.

Under GLBA, non-public personal health information is any information that identifies a person in some way and includes information about that person's health, including the past and present physical and mental health and details of health care and payments for health care. It includes information with respect to chronic or acute conditions, mental health, the types of medication a person takes and the treatments one receives. An insurer must obtain a customer's consent prior to disclosing non-public personal health information to any other party except for items relating to claims management, underwriting and legal investigation or defense, including regulatory compliance or fraud investigation. Under GLBA, the company must provide a disclosure to the customer describing the terms under which customer information will or won't be shared or exchanged with any other person, firm or entity. The disclosure must inform the customer that personal health information won't be shared or disclosed except as permitted by law unless the customer "opts in" and allows such sharing. Conversely, financial information is discloseable unless the customer "opts out" to prohibit disclosure.

Delaware is one of sixteen states that adopted the NAIC model privacy regulation without the health information provisions.[15] One of the reasons Delaware and the other fifteen states were not inclined to adopt the health regulation is that the pending Department of Health and Human Services ("HHS") regulations under the Health Insurance Portability and Accountability Act ("HIPAA") would preempt the field with respect to the disclosure of medical information and that under the model regulation any company or institution in compliance with the HSS regulations would no longer be required to follow the NAIC model regulation. The other reason is that the model privacy regulation issued by the NAIC was not sufficiently comprehensive to allow for adequate enforcement against violators, especially in light of the then pending and now final regulations under HIPAA. One protective aspect of the GLBA privacy regulation is that the insurers and financial institutions subject to that regulation are required to give annual privacy notices updates to their customers with respect to the disclosure of personal financial or health information.

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- Gives patients more control over their health information.
- Establishes standards for the use and release of health records.
- Establishes safeguards which providers and insurers must. achieve to protect such information.
- Establishes civil and criminal penalties for violation of the rule.
- Balances public responsibility for the disclosure of some data for public health protection.

In promulgating the rule, HHS was significantly concerned about how related entities shared health information. For example, information held by a health plan might be passed to a lender who could deny a patient's application for a mortgage or credit card or to an employer who might use it for making a personnel decision. While the rule recognizes the traditional care that the medical profession has taken with respect to the protection of patient records, the rule recognizes that database information is subject to different controls than paper records locked in filing cabinets in secured offices.

Under the rule, every provider will have to establish a procedure for the safeguarding of information including the assignment of a specific person to be responsible for the protection of personal medical health information in each office where such information is collected and stored. There is substantial flexibility for smaller offices to establish tailored plans to fit the particular business practices of that office. Larger practices and insurance companies will need a full-time dedicated person or department responsible for information privacy and security. The more an office will need to share the information it holds with others, the stricter the standards for the protection and security to which that office will be held.

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knowing violations which are subject to criminal penalties, there are three potential penalties: up to $50,000 and one-year imprisonment for obtaining or disclosing protected health information; up to $100,000 and up to five years' imprisonment for obtaining or disclosing protected health information under false pretenses; and up to $250,000 and up to ten years' imprisonment for obtaining protected health information with the intent to sell, transfer, or use such information for commercial advantage, personal gain or malicious harm.

One of the most significant issues for the medical profession is the ability to use personal health information for research or educational purposes. The rule permits special exceptions for the transfer of non-identifiable personal health information for research purposes. The use of personal health information for medical research is linked to the ability of the researcher to mask or depersonalize the information so that the ability to discover or identify the patient to whom the information relates is minimized or prevented. Therefore, research procedures which remove or redact personally identifiable characteristics from the information base, but still permit the necessary health information to be transmitted for statistical and research purposes, would meet the rule's requirements and allow the information to be used without specific consent from the patient.

One aspect of personal health information that receives specific attention in terms of the rule's provisions is the protection for psychotherapist's notes. Traditionally, notes relating to psychiatric treatment are held to a stricter standard of care and privacy than ordinary medical records and have never been shared or exchanged. The rule continues and codifies that higher standard establishing that psychotherapists' notes are not part of the medical record and are never intended to be shared with anyone else.

On March 27, 2002, HHS published proposed changes to the rule.[17] While there is no target date for the publication of a final rule, it must be published before October 13, 2002, to adhere to a requirement that covered entities have 180 days to incorporate changes to the regulation before the compliance date of April 14, 2003 (April 14, 2004 for small health plans).

The most significant change would remove the consent requirements for treatment, payment, and health care operations that could interfere with efficient delivery of health care. Patients would be asked to acknowledge the privacy notice, but doctors and other providers could treat them if they did not. A doctor could discuss a patient's care or condition with another provider without violating the rule if they are overheard. An inadvertent disclosure of a patient's condition or care would not be a violation if a provider or covered entity met the minimum necessary standards and took reasonable safeguards to protect personal health information.

Other changes would require consent prior to sending marketing materials to an individual. Doctors and other covered entities would be permitted to communicate freely with patients about treatment options and other health-related information, including disease-management programs. Greater accessibility to a child's records by parents consistent with state law would also be allowed. The proposed changes would also allow for a single consent for research and information privacy disclosures for research purposes rather than the multiple forms currently required.

The changes would also affect disclosure requirements upon the sale of a business, the disclosure of enrollment information to a plan sponsor, a covered entity's obligation to account for authorized disclosures, expansion or information sharing among covered entities or providers and would provide that protected information does not include employment records.

The insurance industry supports the proposed modifications but claims that the changes do not go far enough. Consumer privacy groups, physicians and Democratic Congressional leaders on health care oppose the proposed modifications and believe that the changes will be a significant blow to patient privacy.

Conclusion

Irrespective of the changes that have occurred in the federal and state laws, the protection and privacy of personal health information continues to be a matter of great concern and high importance to medical professionals, government officials and the lawyers and judges who look to protect the rights of patients, clients and citizens while allowing advances to be made through research and treatment. As we look to medical researchers to find new treatments and cures, the need to share the details of medical care and information becomes more important. The rising costs of medical care and insurance make the efficiencies of technology and information sharing a factor that has to be balanced against the traditional notions of privacy accorded to personal health information. As technology and information sharing systems allow business organizations and commercial support services to share more information more quickly and in different ways, the challenges to assure individual protection will change and require greater vigilance and oversight so that a visit to the doctor won't mean that a credit card will be denied or an automobile premium increased. Current state and federal laws seek to strike a necessary balance among individual privacy, governmental protection, business necessity and scientific advancement. In the final analysis, no matter how sophisticated the technology or how far medical science has progressed in the analysis of data for purposes of care and treatment, there is an overriding concern on the part of health care professionals and state and federal legislators to continue to assure the protection of personal health information through strict controls over the collection, storage and sharing of that information. ◆

FOOTNOTES

1. 16 *Del. C.* §§ 9920 et seq.
2. 16 *Del. C.* §§ 9920(c).
3. 16 *Del. C.* §§ 9926.
4. 16 *Del. C.* Ch. 20.
5. 16 *Del. C.* § 9113.
6. 16 *Del. C.* § 1203.
7. 16 *Del. C.* § 1224.
8. 24 *Del. C.* § 1768.
9. 16 *Del. C.* § 5161(13).
10. 16 *Del. C.* § 1121(19).
11. 18 *Del. C.* § 3820.
12. 24 *Del. C.* §§ 3013, 3913.
13. *In re: The Petition of Greenwood Trust Company*, 1999 WL 167792 (Del. Super. 1999).
14. PL 106-102 (1999).
15. Delaware Insurance Department Regulation 84 became effective on July 11, 2001. *See 5 DE Reg.* 188-204 (7/1/01).
16. 45 CFR Parts 160,164 (2000).
17. *Id.* For the full text of the proposed amendments *see* Vol. 67 of CFR pages 14776-14815 published on March 27, 2002. This article was submitted prior to the end of the thirty-day comment period for the proposed changes. For more information on the proposed changes, *see* HHS Fact Sheet and Press Release Dated March 21, 2002. (All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news.*)

FEATURE

Karen R. Lines

COMMERCIAL COMPLIANCE PROGRAMS FOR THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is increasingly coming under more and more scrutiny for its promotional practices. In part this is due to the ongoing focus on the high cost of prescription products. The recent $875 million settlement of a government investigation by TAP Pharmaceuticals, where the allegations related to false price reporting, violation of the federal laws regulating the use of sample prescription drugs, illegal remuneration to physicians and false price reporting under the Medicaid Rebate Program, also focused the public's attention on the ways in which prescription pharmaceuticals are sold to physicians and reimbursed under government health care programs. It follows that any program to provide prescription drug benefits to Medicare recipients will no doubt include intensified government regulations to ensure that the program properly serves its beneficiaries while avoiding waste and abuse of program resources. Thus, a comprehensive and effective compliance program for commercial activities, one that ensures adherence to the wide variety of laws, regulations and guidelines applicable to such activities, should be an integral part of any pharmaceutical company's commercial strategic plan. In this article, I offer some of my own thoughts on designing and implementing various elements of a commercial compliance program while enhancing the ability of the commercial organization to achieve its goals.

The essential components of a commercial compliance program include the following: (1) designation of a compliance officer and compliance committee, (2) creation of written policies, procedures and controls, (3) effective and periodic training and education of appropriate personnel, (4) well-publicized communication standards and procedures, (5) consistent program oversight, and (6) on-going program maintenance.

1. Compliance Officer and Compliance Committee

Developing a dynamic yet effective compliance program is a major undertaking. It requires a commitment from senior management for the expenditure of time and resources, both financial and human. Designating a compliance officer and compliance committee is crucial to creating a compliance infrastructure so that the development, implementation and maintenance of an effective compliance program have the appropriate level of support within an organization. The compliance officer should have sufficient seniority in the organization to have the authority and the responsibility for bringing compliance issues directly to the attention of senior management. In addition, separating the legal function from the compliance function allows the compliance officer to focus on developing, implementing and maintaining the various components of the compliance program. The legal department's role is to provide advice on the interpretation of laws, regulations and guidelines that govern sales and marketing practices. This then serves as the basis for the development of relevant policies, procedures and controls for the compliance program. In addition, the compliance officer should be responsible for seeing that periodic audits and on-going monitoring of compliance with policies, procedures and controls are performed.

The compliance committee should be comprised of senior

level employees with decision-making authority. These individuals should also be knowledgeable (or make the commitment to become knowledgeable) in the substantive areas of commercial compliance to be able to set compliance policy for the commercial organization. The most compelling reasons to have a compliance committee are that: (1) the committee is recognized by all in the corporation as the body having the responsibility and the authority to set compliance policies, (2) the committee must make the tough decisions on what compliance policy will be for types of activities where the application of legal principles is not necessarily clear, and (3) the cross-functional membership of such a committee will ensure greater buy-in and adoption of the policies. The compliance committee can also serve as a body that helps to determine the protocols for auditing and monitoring commercial activities, investigation and resolution of issues and the identification of problems that may call for preventive or corrective action.

2. Policies, Procedures and Controls

There are many areas of laws, regulations and guidelines that can potentially govern the sale and promotion of a pharmaceutical product. The substantive areas of law that are the most important to guide policy development are Federal Drug Administration (FDA) regulations relating to promotion of prescription products, federal and state laws prohibiting fraud and abuse, and antitrust laws. In addition, there are important laws governing drug samples, the sale of product to government programs and price reporting to such programs, state pharmacy laws and federal and state privacy laws.

The main goal of translating legal guidelines into policies for sales and marketing activities should be to describe how activities should be conducted so that the resulting conduct is within the legal parameters set by the company. This sounds like a simple and straightforward task, but, in fact, it can be quite challenging to accomplish. For example, the federal anti-kickback law prohibits a company from providing any kind of remuneration to a physician in order to induce that physician to prescribe a product reimbursed by a federal government health care program. The law is actually broader than this statement, and subject to interpretation when applied to specific sales and marketing activities. The pharmaceutical industry guidelines on gifts to physicians suggest that it is inappropriate for companies to pay travel and lodging for physicians attending an educational seminar. The guidelines do suggest that companies may pay travel, lodging and honoraria expenses for faculty of such programs. Thus, a company's policies on proper financial support of medical educational programs should be focused on the specific items of expenditure, lest those activities run afoul of the anti-kickback law and/or the industry guidelines.

A partial list of the activities around which commercial compliance policies could be developed may include the following: promotion of products (discussions and use of company approved materials), responding to questions regarding an off-label use, sponsorship of promotional programs, financial support of medical education programs, working with advisors, consultants and speakers, gift giving, appropriate entertainment, working with government accounts, pricing and reporting rules for government programs, contracting with customers for market share and volume incentives, sampling, free goods, billing and reimbursement assistance, and research grants and studies.

Any set of policies should clearly set forth the disciplinary standards associated with violations of the policies. This is another area in which it is sometimes difficult to get a consensus among the interested parties as to what types of violations will be subject to what types of discipline. However, it is well worth the effort because articulating these standards up front sends a clear message that the policies must be complied with and helps ensure consistency in dealing with transgressions that may occur.

Any company should consider including compliance with commercial policies a part of the criteria upon which the performance appraisals of sales and marketing personnel are based. All of this serves to foster a "culture of compliance," which is not inconsistent with success in the marketplace and brings full circle the notion that compliance goes hand in hand with commercial success.

Finally, policies should be published in a manner so that they are disseminated and accessible to all personnel whose job responsibilities are impacted by such guidelines. With the wide use of company intranets, it is now easier and more efficient to publish electronic copies of polices in one central place for convenient and instant accessibility. In addition, it is much easier to update and revise policies that are distributed in electronic form.

3. Compliance Training

One of the largest commitments of time, energy and resources necessary to create an effective compliance program is the need to regularly train appropriate personnel on the policies, procedures and controls. Simply stated, a company needs to decide who needs to be trained, on what topics and policies, how often and in what manner. Advances in training methodology and technology have greatly enhanced the industry's ability to meet this challenge.

Who needs training? Not just sales and marketing personnel! Anyone that is involved in activities that could trigger application of the laws, rules and regulations mentioned above should have some kind of training on commercial compliance policies. For instance, internal support personnel for the sales organization, clinical scientists, medical communications specialists should all be considered for training on commercial policies.

How often should training be conducted and in what manner? As the law and its interpretation or application to commercial activities evolves, a company's policies should change, as well. Therefore, training must be an ongoing and regular effort. Classroom based training, where home office and field people are taken away from their desks or field offices for sometimes days of training, becomes very expensive and time consuming, to say nothing of the logistical challenge in coordinating the training. Therefore, it makes sense for companies to consider the benefits of online and web-based training. Online training modules save the time and expense associated with coordinating and conducting classroom based training. In addition, the curriculum of required courses can be tailored to the individual employee based on his or her job responsibilities or title within the organization. An additional desirable feature is the abili-

ty to electronically track who has been trained and when for ease of record keeping. This provides a basis to audit training activities and determine when updates to training are necessary. From the individual employee's perspective, the online training can be taken at a time convenient to that particular employee's schedule. Finally, most companies that offer online training modules have some ability to link company policies with the appropriate training module. This helps to reinforce the company's position on an issue or particular set of rules.

4. Communication Standards and Procedures

Companies should make sure that employees know whom to contact if they have a question about commercial compliance policies. These calls can be triaged through a company call center or hotline, which can also serve as a place where employees can report, in a confidential manner, suspected wrongdoing. The hotline does not have to be restricted to reports of commercial misconduct. Whatever the breadth or purpose of the hotline, it should be well publicized. And, whether the hotline is staffed internally or outsourced, the rules for triaging different types of inquiries must be carefully developed and implemented.

The rules for confidential reporting of suspected violations of commercial policies should spell out clearly the extent to which the report and/or reporter will be kept confidential, as information may need to be disclosed for purposes of conducting a company investigation. In addition, there should be protocols for logging such calls, for determining the necessity for and conducting investigations, and for resolving identified issues. Since calls to any type of hotline are most often employment related issues normally handled by the human resources department, it is important to involve that department in the development and implementation of a hotline.

5. Oversight

A company's commercial compliance program will rarely be or remain an effective tool for deterring, detecting, responding to and eliminating wrongful conduct without regular analysis of whether, in fact, commercial activities have been conducted consistently with stated policies, procedures and controls. While audits of various components of the commercial policies and controls may be conducted annually, monitoring of certain activities may be conducted periodically throughout the year. For instance, a sampling of documentation relating to funding of educational programs might be reviewed annually or periodically to determine if the programs complied with policies and whether the requisite signatures and approvals were obtained.

A company should consider the following questions when designing this component of the compliance program. What activities will be audited and/or monitored? In what manner will the audit be conducted and with what frequency? Who will be involved in the audit? Will internal personnel or perhaps an external party (an accounting or consulting firm with expertise in the area) conduct it? If internal team members conduct the audit, what functional areas of the organization will be represented on that team? Who within the company will be responsible for seeing that the audit is conducted? What type of report will be generated and with whom will the report be shared? If any issues are discovered during any audit, what are the criteria by which a decision to conduct an investigation is made, and what is the protocol for resolution of any such issues identified?

A pharmaceutical company must recognize that its compliance policies and program cannot remain static. Policies may need to be added, deleted, updated or re-thought to address evolving business practices.

6. Maintenance

The laws and regulations that govern the pharmaceutical industry, and especially the interpretation of those laws, are constantly changing. This is due to evolving business practices, on-going government investigations and settlements, and larger healthcare issues such as the continuing scrutiny of the cost of pharmaceutical products. A pharmaceutical company must recognize that its compliance policies and program cannot remain static. Policies may need to be added, deleted, updated or re-thought to address evolving business practices. Evaluation of the impact of training on employee understanding of and adherence to policies should be performed on a regular basis. Issues of failure to adhere to policies identified through auditing or monitoring efforts, or through reports to a company hotline, need to be investigated and resolved. Again, the compliance officer has an important role to play in making sure that the compliance program is kept up to date. Likewise, the compliance committee, or a group of individuals to which such duties are delegated, can provide input and buy-in for the decisions on how and in what manner to update the various components of the program.

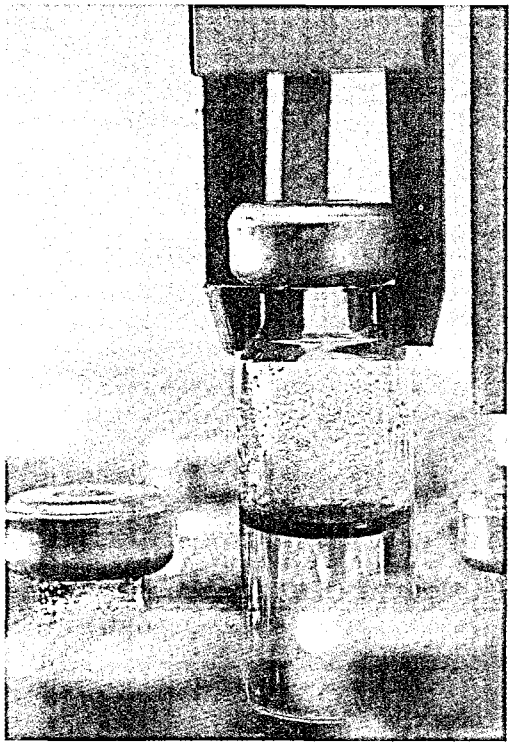
Conclusion

In the months and probably years to come, there will be no lack of attention directed toward the pharmaceutical industry, especially its sales and marketing practices. It is incumbent upon the industry to conduct itself according to all the laws, regulations and guidelines that govern its promotional activities. This can only be accomplished with an effective compliance program aimed at preventing, detecting and addressing commercial activities that violate or are inconsistent with such laws, regulations and guidelines. However, it matters little how many resources and how much time is spent designing such a program. It will not be effective unless it also supports a company's business and commercial objectives, and takes advantage of embedding compliance into optimal business processes. ◆

Mike Castle

BIOMEDICAL RESEARCH: A SUCCESS IN CONGRESS AND IN DELAWARE

As we all know, too often we don't hear about good news or success stories. The nightly news and daily headlines are primarily dominated by crime and accidents, not stories about the local school crossing guard helping children or the lady who helped her elderly neighbor next door. Perhaps this is inevitable. Scandals and tragedy readily grab our attention. The same holds true for what happens in Congress. As I write this column today, the big news in our papers and on our televisions is the partisan sniping on campaign finance reform, the budget and the president's judicial nominees.



However, there is also positive news on an issue that can help Americans in their daily lives. One of the real success stories in Congress over the last few years is support for medical research. Disease touches all our lives, as patients or as the relative or friend of someone suffering from a serious illness. We form coalitions, patient advocacy groups, and support groups and work with doctors, pharmacists and hospitals to address the medical needs that impact our lives. We all know someone who has suffered from cancer, Alzheimer's, diabetes, heart disease or HIV and we deeply want to help treat them and to find cures to save the next generation.

Fortunately, the United States is home to the cutting edge in medical research — The National Institutes of Health (NIH), which supports the best and brightest scientists and researchers attempting to solve one of the greatest mysteries in the world, the cause and cure for deadly disease. Americans are greatly interested in health information, new medical discoveries and new scientific discoveries. When asked, Americans rate medical research equal to or greater in importance than other national programs in terms of deserving federal support — the only exception is public education.

Every year I meet with dozens of groups of Delawareans who are working to help fight a major disease. These advocacy groups know the value of medical research. While they are not united necessarily on how this funding should be spent, they are united in their call for increased funding to help develop treatments for our most deadly diseases. These meetings are also the most heart-wrenching I have, children who are suffering daily with insulin treatments to treat their diabetes, patients weakened from recent chemotherapy treatments, and Delawareans whose parents are suffering from Alzheimer's disease.

I am proud to say the Congress of the United States, even during the toughest of budget times, has had the will to commit to doubling the funding for medical research over a five-year period. This year, we will meet that commitment. Since Fiscal Year 1999, Congress, with my strong support and urging, has increased funding for disease research by an average of 15 percent each year bringing the total possible funding for this year to $3.7 billion. Just seven years ago, federal funding for medical research was a little over one-half billion dollars.

Many argue that the funding should be allocated according

to disease, but the truth of the matter is Congress is not comprised of 435 medical researchers who have the greatest knowledge of which disease should receive which level of funding. My goal is not to micro-manage the funding, but to merely help determine how much funding NIH receives as a whole. Science, not politics, should drive medical research spending. Congress should never put itself in the place of being courted by the most powerful lobby or the fad of the moment. Our job is to allocate the funding to ensure research is conducted to help the most people throughout the world.

This historic increase in funding has done just this — we have moved forward with new opportunities to understand disease, progress, new treatments and knowledge. It has not gone into a black hole. As a budget hawk who believes federal funding should have some form of accountability attached to it, I believe this funding is doing nothing but speed up progress across all diseases. For instance with this increase in federal funding, more than 30 genes for human diseases and disorders, including various cancers, deafness, and birth defects have already been identified and scientists are using this information to design better means of diagnosing and treating those disorders and of identifying other genes.

Some other examples of progress include a project by the National Institute on Drug Abuse to jump-start the establishment of what has become the national infrastructure for testing treatments for drug addiction. NIH also was able to establish the National Center on Minority Health and Health Disparities whose job is to coordinate research on racial and ethnic disparities and conduct studies related to medically underserved populations, including rural areas.

NIH also extends many grant opportunities to local organizations, medical colleges and research institutes. I strongly believe that Delaware has the potential to become the next major biomedical research, management and education center in the country. Just last November, I celebrated with the Delaware Biotechnology Institute and Delaware institutions of higher education a $5.8 million grant from NIH to bolster biomedical research in the State of Delaware. This grant is being used to establish the Biomedical Research Infrastructure Network to process and analyze the nation's biological research and to enable researchers, schools, faculty and students on the network to take advantage of this. This network is just one example of Delaware's developing role in the area of biomedical research. Delaware companies, such as Astra-Zeneca, DuPont and Agilent Technologies have put us on the forefront of biomedical research and development.

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As the era of biomedical research moves forward, we must continue to improve public knowledge and awareness of advances in biomedical research. Such increased knowledge and awareness can be beneficial to so many of us. Information dissemination and stronger working relationships with the practicing physicians, hospitals, pharmaceutical companies and the public as a whole, should continue to be a high priority of NIH and all biomedical research institutions.

Times have changed in the past 100 years and we are a much healthier society, living longer and with a chance to beat many diseases. Although each of us fears our own mortality, we should take comfort in the progress by NIH and know that we are extremely fortunate to have a brain trust working together to reduce disease for all Americans. ◆

FEATURE

Stephen T. Lawless
Margaret McSoley Coupe
Dana L. Ferrell

BALANCING HEALTH CARE NEEDS FOR THE CHILDREN OF DELAWARE

As a nation, we pride ourselves on our devotion to the well-being of our children. Yet in the United States, an estimated 8.5 million, 11.6% of the nation's children, are completely uninsured.[1] Children need continuous access to quality health care services. A vital part of that access is having adequate health insurance — whether private or public. Even those fortunate enough to have any coverage depend on an uneven, fragmented, and weakly funded patchwork quilt of programs and services.

According to a recent Institute of Medicine report, "Insurance coverage is the major determinant of whether children have access to health care." Further, the report cited many studies showing that children without health care coverage are less likely to receive medical care when injured, less likely to receive treatment for illnesses, more likely to be sick as newborns and less likely to receive immunizations as preschoolers.[2] These factors impact school attendance and may affect educational performance and opportunities. There is a growing body of evidence showing that early intervention and prevention can lessen the damage caused by untreated illnesses and developmental delays.

Just having health care coverage — "an insurance card" — does not ensure access for children. The same Institute of Medicine report found that if the child is in an underinsured family, the child is less likely to receive care because the family is not used to utilizing the health care system. Other barriers to accessing care found by the Center for Studying Health System Change include lack of a "medical home," insufficient transportation, and lack of available, appropriately trained physicians. Due to these and other barriers, the Center estimates that as many as 21 million children are at risk of not being able to receive health care services or have access problems.

Medicaid is a medical assistance program that pays for health care in eligible categories (elderly, blind, disabled, and families with children) within varying income standards. The federal government and the states fund the program. In 1996, Medicaid insured almost 30 percent of the nation's children under 21 years of age.[3] Due in part to welfare reform, Medicaid eligibility has been expanded since that time; however, private insurance coverage has declined.

In an effort by the federal government to provide insurance coverage to more children, the State Child Health Insurance Program ("SCHIP") was introduced in 1997 and enrolled 3.3 million children through fiscal year 2000. However, with the current economic recession and tight state budgets, many states have frozen or curtailed enrollment in this program.[4] This is an example of how the fragmented approach to funding children's health care leaves families and children behind when they may need the most help.

Many physicians do not participate in Medicaid/SCHIP or, if they do, limit the number of these patients they are willing to treat because of the low reimbursement rates, as well as the added burden of Medicaid regulations and paperwork. Because the programs vary from state to state and eligibility rests on fluctuating family income, children drift in and out of coverage.

There are approximately 59,000 pediatric Medicaid patients in Delaware; 21% of the State's under 18 population. Nemours, through AIDHC and NCCW, is now providing services to a vast majority of the Medicaid population throughout the State of Delaware.

The problems serving children with Medicaid coverage are often compound. Children in publicly funded programs may be sicker than more fully and continuously insured children and have underlying health problems that frequently require more intensive services for more complex conditions. For newly enrolled Medicaid patients, there are often past health care deficits that must be addressed. These problems and associated costs, coupled with the additional

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TIONS FOR CHILDREN'S IN ALL STATES

hould have access to
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tion and early intervention which are key to the health and well-being of our children.

- Children should have continuous coverage and access to health care services. Continuity of care is integral to effective, quality health care services.
- An adequate choice of health care providers should be available for the care of children and should include pediatricians and pediatric subspecialists when available.
- Children with complex and or chronic illness need comprehensive care tailored to their needs.
- Children should not lose health care coverage or access to health care services due to the bureaucracy or to restrictions related to eligibility guidelines. ◆

administrative burden imposed by Medicaid, discourage providers from taking care of these needy children.

Office holders will avow publicly that children hold the keys to America's future, and that healthy children will become more productive citizens and better taxpayers than those left behind by inadequate funding and limited access to needed care. However, it is an empty promise for the state to offer healthcare coverage and benefits for more children through Medicaid or SCHIP and then provide inadequate funding for services. The nation has an obligation to provide realistic reimbursement guidelines for services rendered by the providers in any state, and there should be no negative bias associated with age. It is difficult to justify a significantly lower payment for children's health care services under federal/state Medicaid programs than the federal Medicare program pays for treating their entitled grandparents. Yet that is exactly what prevails in this country. Medicaid funds pay for care at approximately half of the rate that Medicare does for the same service.

Nemours is cognizant that, with increased access, tradeoffs often occur in either quality or cost. Nemours has specifically tracked satisfaction of services provided to the Medicaid population. Nemours demonstrates very high marks that are consistent with the results of commercially insured patients. And Nemours supports an ambitious program of clinically related pediatric research, as well as education and communications programs designed to improve family knowledge about children's health. The organization has committed substantial resources to medical and information technology and Continuous Quality Improvement. The result is more satisfied patients and families, as shown by the percent of patients "very satisfied" with care, along with better outcomes from the family-oriented healthcare team. A recent poll of patients determined that the Alfred I. duPont Children's Hospital of Nemours was consistently ranked in the 99th percent for patient satisfaction — see chart above (Jackson Organization).

This experience and performance in children's health motivate Nemours to offer observations about ways to achieve better balance in public delib-

FOOTNOTES

1. NACHRI/Census Bureau report.
2. Institute of Medicine, "America's Children: Health Insurance and Access to Care" (1998), p.3.
3. American Academy of Pediatrics.
4. Ornstein, Charles (2002, Feb 25) "States Cut Back Coverage for Poor." *L.A. Times*, retrieved 2/26/02. *www.latimes.com/news/printedition/front/la-000014485feb25.story?coll=*.

ABOUT THE NEMOURS FOUNDATION

The Nemours Foundation is one of the nation's largest non-profit organizations dedicated to providing high quality healthcare services for children and the largest non-profit pediatric specialty physician practice without government affiliation. Established in 1936 through a trust created by philanthropist Alfred I. duPont, Nemours operates comprehensive multispecialty pediatric practices throughout Florida, the prominent Alfred I. duPont Hospital for Children in Delaware, and numerous primary care pediatric practices throughout the Philadelphia, Delaware, and Central Jersey regions. In Delaware, care is delivered via the 152-bed Alfred I. duPont Hospital for Children (AIDHC), the only hospital dedicated to the 201,000 children in Delaware, and the Nemours Children's Clinic (NCCW) in Wilmington serving the Philadelphia/ Wilmington and South Jersey areas. The 29 primary and 158 specialty physicians in this area oversee over 6,900 acute inpatient admissions, 8,800 surgical cases and 31,000 inpatient days per year along with 324,000 outpatient primary and specialty care visits annually.

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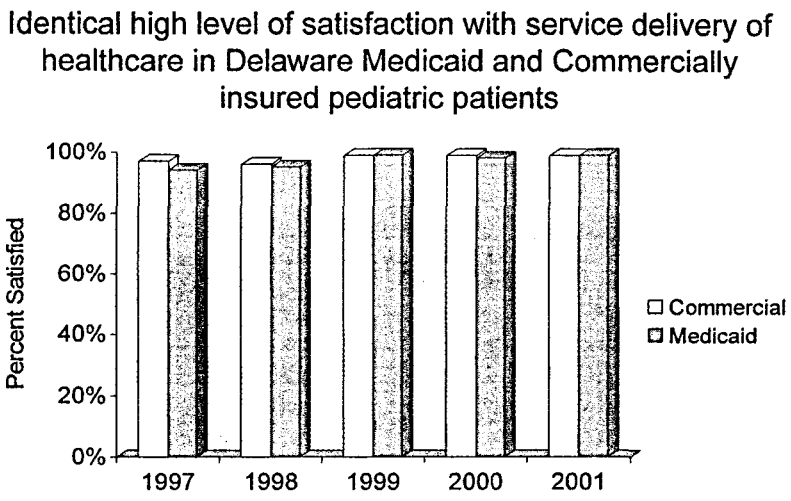

Source: Nemours Office of Operational Assessment satisfaction tracking data

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This experience and performance in children's health motivate Nemours to offer observations about ways to achieve better balance in public deliberations on health care policy.

Delaware can take the lead.

Already ahead in percentages of children covered and with a more comprehensive system of healthcare access in place than many states, Delaware can continue to be a leader by providing access to healthcare for all children in the State. Delaware can expand services to increase the probability that children in our State have adequate health services — an integral part of their becoming fully functional, productive citizens of the future.

Recommendations for Children's Health Care in All States

- Children should have access to health care services that include prevention and early intervention which are key to the health and well-being of our children.
- Children should have continuous coverage and access to health care services. Continuity of care is integral to effective, quality health care services.
- An adequate choice of health care providers should be available for the care of children and should include pediatricians and pediatric subspecialists when available.
- Children with complex and or chronic illness need comprehensive care tailored to their needs.
- Children should not lose health care coverage or access to health care services due to the bureaucracy or to restrictions related to eligibility guidelines. ◆

FOOTNOTES

1. NACHRI/Census Bureau report.
2. Institute of Medicine, "America's Children: Health Insurance and Access to Care" (1998), p.3.
3. American Academy of Pediatrics.
4. Ornstein, Charles (2002, Feb 25) "States Cut Back Coverage for Poor." *L.A. Times*, retrieved 2/26/02. *www.latimes.com/news/printedition/front/la-000014485feb25.story?coll=*.

ABOUT THE NEMOURS FOUNDATION

The Nemours Foundation is one of the nation's largest non-profit organizations dedicated to providing high quality healthcare services for children and the largest non-profit pediatric specialty physician practice without government affiliation. Established in 1936 through a trust created by philanthropist Alfred I. duPont, Nemours operates comprehensive multispecialty pediatric practices throughout Florida, the prominent Alfred I. duPont Hospital for Children in Delaware, and numerous primary care pediatric practices throughout the Philadelphia, Delaware, and Central Jersey regions. In Delaware, care is delivered via the 152-bed Alfred I. duPont Hospital for Children (AIDHC), the only hospital dedicated to the 201,000 children in Delaware, and the Nemours Children's Clinic (NCCW) in Wilmington serving the Philadelphia/ Wilmington and South Jersey areas. The 29 primary and 158 specialty physicians in this area oversee over 6,900 acute inpatient admissions, 8,800 surgical cases and 31,000 inpatient days per year along with 324,000 outpatient primary and specialty care visits annually.

Dana K. McKenzie
Susan F. Paikin

A COMPLETE HISTORY OF MEDICAL CHILD SUPPORT — SLIGHTLY ABRIDGED!

Whether and how to ensure health care coverage for all Americans has been and will continue to be the subject of headline-making, hand-wringing, heated political debate. However, nearly everyone agrees that there is a critical need to ensure that all children receive adequate medical and dental care.

To gain a better understanding of the policy and practical roadblocks to health care for children living in single-parent families, it is useful to recall how we arrived in our current circumstance — wherein too many of these children have no health care coverage or are covered by a plan that is geographically or otherwise impractical.

From the Beginning of Time (at least the authors' lifetimes) Through the 60's

Up through the 1960's, the structure of society and the roles men and women played remained remarkably constant. Men worked; women didn't — or at least women weren't generally recognized as "working." Working men stayed at one company throughout their careers. In exchange for their hard work and loyalty, the company provided traditional, fee-for-service health insurance for the man and his family. Separation and divorce occurred, but given the primarily fault-based grounds, such breakups were neither commonplace nor widely accepted. Children born out of wedlock were rarely legitimized and even more rarely gained access to the employment benefits available to the father's family through his employer. They were frequently left to the care of the existing welfare system — which at least offered a lifetime entitlement.

Congress first authorized publicly subsidized children's health care coverage through Medicaid in 1965.[1] Nonetheless, low-income families were often dependent on the charitable work of organizations such as the Nemours Foundation for serious medical needs.[2]

Things Changed . . .

By the mid-70's, gender roles were no longer so clear-cut and corporations grew less paternalistic. Women entered the workforce in record numbers. The "company man" — or woman — would now work for many employers over a lifetime, by choice or necessity. Traditional insurance was replaced by the omnipresent Health Maintenance Organization ("HMO"), setting up provider networks and limited service areas.

Meanwhile, no-fault divorces and out-of-wedlock births skyrocketed. And welfare (then Aid to Families with Dependent Children, or "AFDC") changed from a program to help war widows to one responding to the needs of millions of poor children in divorced, separated and never-married families.

In response, on January 4, 1975, after three years of Congressional discussion, the Child Support Enforcement Program was created under Part D, Title IV of the Social

Security Act. Hence the shorthand reference to this federal/state/local partnership as the "IV-D Program." The IV-D program locates noncustodial parents; establishes paternity; establishes, modifies and enforces child support orders; and collects and distributes child support. The agency's services are obtained either by paying an application fee of $25 or less (as set by each state) or through co-operation requirements imposed when welfare benefits are obtained. The federal Office of Child Support Enforcement ("OCSE") is housed in the Department of Health and Human Services ("HHS"), Administration for Children and Families ("ACF"). Delaware's IV-D agency, the Division of Child Support Enforcement ("DCSE") comes under the Department of Health and Human Services.

Beginning with the Child Support Amendments of 1984,[3] state IV-D programs were required to petition for medical child support in all IV-D cases in which such coverage is *available at reasonable cost.* As directed by Congress, the Secretary of HHS defined "reasonable cost" by regulation. *The cost of health care coverage is reasonable if it is available through the child support obligor's employment.*[4] Regulations also require that each state's presumptive child support guideline take into account children's health care needs when a child support order is established.[5] Delaware's Melson formula has done so since its statewide adoption almost 25 years ago.

Other early legislative efforts were designed specifically to assist in reducing the cost of providing publicly funded health care coverage through the Medicaid program. All Medicaid beneficiaries applying on behalf of children in single-parent families were required to assign their medical support rights to the state and cooperate with the child support enforcement program.[6]

. . . And Keep Changing

The task of securing and enforcing health care coverage for IV-D children grew even more challenging — in part due to continuing changes in the structure of the labor market. To a significant extent, in the last decade the fundamental employer-employee relationship has changed as we have moved toward a "consultant" economy. The percentage of America's workforce that receives employer-provided health care coverage is shrinking. Employees now find themselves downsized altogether or reclassified as independent contractors. In the economy's growing service sector, health care benefits are rare even for full-time employees. And for many, full-time work is achieved only through cobbling together two or three part-time jobs.

This reduction in employer-sponsored health care coverage coincided, not coincidentally, with the skyrocketing cost of health insurance. Even when a noncustodial parent's employer offered health insurance benefits, the share paid by the employee for family coverage was often beyond the family budget. And the cost of obtaining health care benefits on one's own was out of the question for all but the most successful self-employed or small business owners. The high cost of medical, dental, mental health and prescription therapy, coupled with the large number of uninsured children, make the apportionment of health care costs contentious at best and, too often, an empty promise. As for Medicaid, the steady drop in reimbursement rates has reduced the number of providers willing to accept new patients.

The percentage of America's workforce that receives employer-provided health care coverage is shrinking. Employees now find themselves downsized altogether or reclassified as independent contractors.

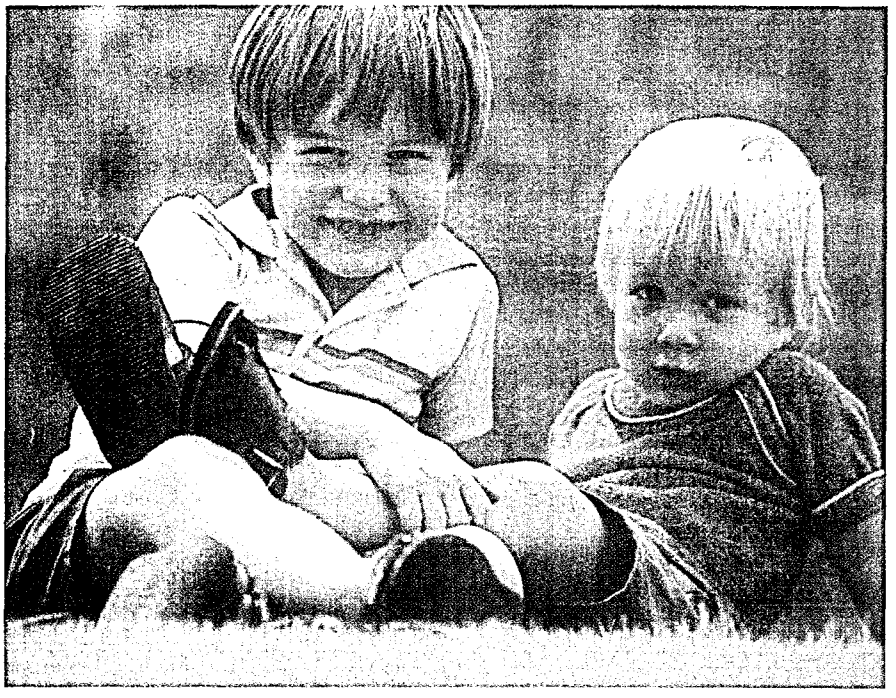
Over the past seven years, Congress has again sought to strengthen medical child support enforcement and remove some of the impediments to providing children with health care coverage. The *Omnibus Budget Reconciliation Act of 1993* ("OBRA '93")[7] amended the *Employee Retirement Income Security Act of 1974 ("ERISA")*, creating the *Qualified Medical Child Support Order ("QMCSO").*[8] Every employer group health plan must honor a properly prepared QMSCO that requires a plan participant to provide coverage for a dependent child.[9] A QMCSO may be a judgment, decree, or order issued by a court of competent jurisdiction through an administrative process that has the force and effect of law, or an administrative notice that is issued through such an administrative process.

A new ERISA §1908 required states to enact laws prohibiting employers and insurers from denying enrollment of a child under a parent's family health coverage plan due to various factors such as: the child was born out of wedlock, the child was not claimed as dependent on the parent's federal income tax return, or the child does not live with the parent or in the insurer's service area.[10]

Three years later, the *Personal Responsibility and Work Opportunity Reconciliation Act of 1996 ("PRWORA")*[11] (generally known as "welfare reform") required a provision for health care coverage in all child support orders. (As noted earlier, IV-D agencies were required previously to simply petition for the inclusion of medical support in new and modified support orders when health care coverage was available to the noncustodial parent through employment-related or other group family health coverage.)

States were also required to provide for a simple administrative process for enrolling a child in a new health plan involving the use of a notice of coverage, which operates to enroll a child in a new employer's health plan. And §609(a) of ERISA was amended to expand the definition of "medical child support orders" to permit certain administrative orders to be considered QMCSOs, rather than just court orders.

Recognizing that Medicaid was insufficient to meet the needs of uninsured children in low-income families, Congress passed the Balanced Budget Act of 1997,[12] creating Title XXI of the Social Security Act and establishing the *State Children's Health Insurance Program ("SCHIP").* This program provides funds and establishes a flexible



Child support enforcement, including maintaining health care coverage, remains a linchpin for the economic security of single-parent households.

administrative framework that enables States to operate their respective SCHIP programs as an extension to the Medicaid Program, as a separate entity, or as a combination of these two approaches. Still, while these programs provide essential coverage for many low-income children, they simply do not provide health coverage for millions of uninsured children whose family incomes exceed the threshold — generally less than 200% of poverty.

Moving back to enforcement, Pub. L. 105-200, the *Child Support Performance and Incentive Act of 1998 ("CSPIA")* mandated steps to improve medical support enforcement in the IV-D program, including:

- Establishment of a Medical Child Support Working Group ("Working Group") by the Secretaries of HHS and Labor to identify impediments to the effective enforcement of medical support by State IV-D agencies and make recommendations to eliminate them;
- Development and promulgation by HHS and Labor of a *National Medical Support Notice ("NMSN")*, to be issued by State IV-D agencies as a means of enforcing health care coverage provisions contained in child support orders;
- Amendment of ERISA to require the administrator of a noncustodial parent's employment-related group health plan to deem an appropriately completed Notice (that also satisfies the QMCSO requirements) to be a QMCSO for the child and to implement coverage in a timely manner.[13] This "deeming" provision and time-limited responses are critical to the IV-D agency's implementation of medical support in an expeditious and automated fashion;
- Development and issuance by HHS and Labor of interim and final federal regulations which include appropriate procedures for the transmission of the NMSN to employers by State IV-D agencies; and
- Submission to Congress of a joint report from HHS and Labor, addressing the recommendations of the Working Group and assessing the NMSN.

A New Medical Child Support Paradigm

The Working Group included representatives of the federal government, employers, health plan administrators, the health insurance industry, child support professionals, SCHIP and State Medicaid programs, payroll professionals, unions, courts, and advocates for parents and children. It met eight times starting in March 1999 and reached consensus on 76 recommendations, discussed in detail in its 250-page report submitted to Secretary Shalala, HHS, and Secretary Herman in June 2000.[14]

From the beginning, the Working Group recognized that the current medical child support regulations were based on assumptions that were no longer true or appropriate and did not meet the need of either the custodial or noncustodial parent — or the child, in many cases. Today, either parent may have custody; both parents often work; and one, both or neither parent may have access to employment-based family health insurance.

Aside from its direct medical support provisions, PRWORA wrought a fundamental change in the concept of welfare — from an entitlement program to *Temporary Assistance to Needy Families ("TANF")*. Starting in 1996, welfare benefits became time limited and all recipients are now expected to work. Child support enforcement, including maintaining health care coverage, remains a linchpin for the economic security of single-parent households. This is true of families across much of the economic spectrum, not just low-income households.

The implications of this policy shift are particularly noteworthy in 2002. Though state and federal governments, including Delaware's, rightfully tout the dramatic decline in the number of welfare recipients, many who have not managed to leave TANF successfully now face the expiration of their benefits. Others may be forced back on welfare if unemployment continues to rise and the economy slows.

In addition to the flawed assumption that custodial parents don't work or don't have access to health insurance, other assumptions challenged by the Working Group include:

- Employment and health care coverage are stable;
- Dependent care coverage is available and the cost is reasonable;
- Distance from the noncustodial

parent doesn't matter; and

• Most Medicaid/SCHIP enrolled children could have private coverage.

In lieu of these assumptions, the Working Group offered a new paradigm for Congress and policy-makers to consider (see box below).[15]

Discussion of the Working Group's 76 recommendations is obviously well beyond the allowable space of this publication or the patience of the reader. However, the focus of those recommendations — that is, determining whether and how to allocate medical insurance and other costs when calculating the parents' child support obligation — illustrates the move from old assumptions to new principles.

Recall that current federal law and regulations require that medical support be included in all new or modified orders entered after implementation of welfare reform. Federal regulations still direct that the obligor be required to provide health care coverage for his or her child if such coverage is available through employment. No consideration is given to whether such private insurance is accessible to the child or affordable despite an employer subsidy. Nor does it factor in whether the child's custodian has better coverage, whether requiring the obligor to pay for coverage will significantly lower needed cash support, or whether the government will save even a dime in Medicaid/ SCHIP costs. The Working Group concluded that for many, following this regulation is a lose, lose, lose result for all involved — including the government.

The Working Group recommended that a decision maker (regardless of whether it is a court or administrative hearing agency) first determine whether health care coverage *available to either or both parents* is *appropriate* — that is, *comprehensive, accessible, and affordable.* Medicaid/SCHIP should not relieve parents of the responsibility to provide health care coverage for their children or replace private insurance, but should serve as the payer of last resort.

• Private coverage is *affordable* if the cost does not exceed five percent of the providing parent's gross income.

• Private coverage is *accessible* if it will be available for at least one year and the child lives within the geographic area covered by the plan or primary care is available within 30 minutes or 30 miles of the child's home.[16]

• Coverage is *comprehensive* if it meets the child's basic needs.

The selection of which *appropriate* coverage to order would be based on a decision matrix that considers the private insurance available to both parents. If such coverage is available through one parent, he or she should enroll the child. If both parents have

THE WORKING GROUP'S NEW PARADIGM

Increase the Number of Children in Single-Parent Households with Health Care Coverage	It is in the best interest of both children and the nation that the maximum number of children have access to health care coverage. Lack of such coverage affects children's current and future health and their ability to be productive citizens. Moreover, when lack of care leads to poor health, the short- and long-term costs to employers, insurers, and publicly-funded health programs such as Medicaid and Medicare increases.
Appropriate Private Dependent Health Care Coverage Comes First	Parents share primary responsibility for meeting their children's needs. When one or both parents can provide comprehensive, accessible, and affordable health care coverage that coverage should be provided to the child.
Look to Both Parents as a Source of Coverage	Coverage available to both parents should be considered in setting a medical support obligation. If only the custodial parent has coverage, that coverage should be ordered and the noncustodial parent should contribute toward the cost of such coverage. When both parents are potentially able to provide coverage, the coverage available through the custodial parent (with a contribution toward the cost by the noncustodial parent) should normally be preferred as it: 1) is most likely to be accessible to the child; 2) involves less difficulty in claims processing for the custodial parent, the provider, and the insurer; and 3) minimizes the enforcement difficulties of the child support agency or private attorney responsible for the case.
Affordable Coverage	In deciding whether to pursue private coverage, the cost of coverage should be considered. To the maximum extent possible, public dollars (through, for example, enrollment in Medicaid/SCHIPs) should be the payment of last resort. However, private insurance should not be ordered when its cost significantly lowers the amount of cash support available to meet the child's basic needs and the child is eligible for some other form of coverage.
Accessible Coverage	When private health care coverage is available to a child, the child support enforcement agency should consider the accessibility of covered services before it decides to pursue the coverage. Children should not be enrolled in any plan whose services/providers are not accessible to them, unless the plan can provide financial reimbursement for services rendered by alternate providers.
Seamless Coverage	The child support (IV-D) program should work in close conjunction with Medicaid/SCHIPs to ensure that children who have access to private coverage obtain such coverage, and those who are eligible for publicly-subsidized coverage are covered by Medicaid or SCHIPs.

access to appropriate coverage, the custodial parent should provide it.

Regardless of which parent provides the insurance, the costs would be allocated according to child support guidelines. Each state would be required to incorporate in its child support guidelines a clear method of adjusting child support awards to account for health-care premiums. Child-support orders would specify how such amounts are to be allocated between the parents.

When coverage is not available from a parent, the Working Group recommended considering a stepparent's coverage, a subsidized program such as Medicaid or SCHIP, or an alternate low-cost child-only plan. Decision makers may order parents to seek public coverage when neither has appropriate private coverage.

For unreimbursed child-health-care costs, the Working Group recommended that states: (1) grant the decision maker authority to apportion uncovered costs; (2) apportion costs not included in the child support order on a pro-rata basis; and (3) develop protocols to expedite determination and payment of these costs.

Why Any of This Matters

While much of the work suggested by the Working Group's report will fall into the laps of legislators and executive branch employees of the federal and state governments, there is much in the Working Group's recommendations that will impact employers, health insurance companies, benefit plans, health providers, and individuals negotiating or litigating child support matters in the context of a divorce or paternity action.

Although two years have passed since *21 Million Children's Health: Our Shared Responsibility* was submitted, it appears that Congress will receive the Administration's recommendations and assessment in sufficient time to consider action on them this year, likely during the welfare reauthorization debate that will take place this summer. The Working Group's report and its recommendations reflect the principle that access to adequate health care coverage during childhood may have profound lifelong ramifications. The social, policy and practical issues raised by these discussions are timely and important — to us as parents, citizens and lawyers. ◆

FOOTNOTES

1. Medicaid, the largest health insurer in the United States, provided health coverage for 20.8 million children by 1998. Annual Medicaid expenditures for American children (including premium payment for prepaid health care) were $26.2 billion, an average of nearly $1,260 per enrolled child. Approximately 40 percent of children who are eligible for IV-D services participate in the Medicaid program.

2. See the article by Dr. Steve Lawless in this issue of *Delaware Lawyer*.

3. Pub. L. 98-378.

4. 45 CFR sections 302.80, 303.30 and 303.31 (1990).

5. 42 U.S.C.§667(b) (1998). The State guideline applies to all orders for child support whether or not the custodial parent is receiving services under the IV-D Program.

6. This requirement was later modified to exclude pregnant and post-partum mothers. Child support and Medicaid agencies were allowed to enter into cooperative agreements to pursue medical support assigned to the state, and child support agencies were required to notify Medicaid agencies when private family health coverage was obtained or discontinued for a Medicaid-eligible person. 45 CFR 303.30 and 303.3.

7. Pub. L. 103-66.

8. We included a crossword puzzle of acronyms mentioned in this article; it was fortunately cut for space. Remember, we are dealing with government programs here.

9. ERISA of 1974 as amended. 29 U.S.C. §1169(a)(1998). The QMCSCO is available both for orders enforced by a IV-D agency and those enforced directly by the custodial parent.

10. Also, state Medicaid agencies were permitted to garnish wages, salary, or other employment income, and withhold state tax refunds from any person who is legally obligated to provide medical support for a child eligible for medical assistance under Title XIX, and who has received payment from a third party but has not reimbursed either the other parent or guardian of the child or the provider of the services.

11. Pub. L. 104-193.

12. Pub. L. 105-33.

13. A NMSN is still subject to all of the procedural requirements that any QMCSO is subject to, including a determination by the plan administrator of whether it is qualified. Custodial parents seeking to enforce the medical child support obligations of the noncustodial parent through their own means will continue to present the court or administrative order to the group health plan for a determination of whether it is a QMCSO.

14. The full report, *21 Million Children's Health: Our Shared Responsibility*, is well worth reading and can be found on OCSE's website at http://www.acf.dhhs.gov/programs/cse/rpt/medrpt/index.html.

15. The "Working Group's New Paradigm" chart is from pages 2-19 of the MCSWG Report.

16. A state should be permitted to adopt the Medicare standard or other alternatives.

The Importance Of An Independent Judiciary And A Free Press

ROBERT KLEINER

(Continued from page 24) the great importance of a free press and a judicial branch of government, but the Bush administration has chosen to bend the rules to justify trying supposed members of al-Qaeda. The point in question is whether or not foreigners being tried by the United States are entitled to the same rights and privileges as American citizens are, as applied to our legal system.

Regardless of the answer to this ethical dilemma, to be tried in a civil court, where our rights are protected through a free press and an independent court system is something that all American citizens deserve. The consequences of removing this right, as our Forefathers predicted, would be chaotic. ◆

ANDREW ROSS SILVERMAN

(Continued from page 24) observation of the importance of freedom of the press when he said: "Were it left to me to decide whether we should have a government without newspapers, or newspapers without a government, I should not hesitate to prefer the latter."

The first amendment of the Constitution states that the government cannot institute a law prohibiting the exercise of a free press. Free press is a salient method Americans use to express opinions and complaints about the government. Without this freedom, government officials can control information, and therefore the thoughts and action of its citizens. Government then changes not on the free will of the people, but on the ideas of a select few. The Sedition Act, approved on July 14, 1798, prohibited the press' right to criticize government and was later deemed unconstitutional. The act did not allow the people to convey to the government the need for change.

Were it not for these two freedoms, an independent judiciary and a free press, the United States would betray the very principles it fought for in its war against Great Britain during its tyranny over the colonies. These two fundamentals of a free American society should be honored and cherished and under no circumstances called into question. Free speech and free judiciary contribute to American government being a legitimate popular, representative government. ◆

BAR BENCH MEDIA CONFERENCE ESSAY CONTEST WINNERS

The Bar Bench Media Conference of Delaware, formed in 1975, was designed to develop and foster the mutual understanding essential for the conduct of fair and impartial court proceedings without encroachment upon the freedom of the press. Currently chaired by President Judge Henry duPont Ridgely, the Conference consists of representatives of the Delaware electronic and print media, judiciary and legal community. The Conference serves as a unique forum for discussing matters of concern to media representatives, lawyers and judges.

This spring, the Conference sponsored a 500-word essay contest for 11th and 12th grade Delaware public high school students on the importance of an independent judiciary and free press. The winning essays were written by Robert Kleiner, a senior at Concord High School, and Andrew Ross Silverman, a junior at Dover High School. Chief Justice E. Norman Veasey honored the winners at separate ceremonies in Wilmington and Dover. Each winner received a $500 stipend and the opportunity for a series of one-day internships with a Delaware justice or judge, a Delaware lawyer, and an electronic and print media representative.

***Delaware Lawyer* is pleased to publish the winning essays.**

The Importance Of An Independent Judiciary And A Free Press

BY ROBERT KLEINER

Freedom of the press and an independent judiciary are two of the most revolutionary ideas written into the Constitution. A free press and court system are the ultimate safeguards of our unalienable rights.

Where there is no free press or independent judiciary, liberty cannot be ensured. A recent example of this statement is shown through special military tribunals being used by the Bush administration to try alleged terrorists. The media is banned from witnessing the tribunals. Furthermore, the trials are conducted completely under the authority of the executive branch.

In these trials, the odds are stacked in favor of the prosecution. One branch of government plays the role of judge, jury, and prosecutor, an ideological conflict of interest. Other nations have spoken out about our use of secret military tribunals. Alexa McDonough of Canada's Parliament wrote, "To decide to give any nation or any coalition of countries, no matter how broad, the right to act as judge, jury, and executioner when dealing with horrendous crimes is simply not acceptable." McDonough argues that suspected terrorists should be given a trial by the United Nations, rather than subjected to military tribunals.

The problem that McDonough spoke of is not present in our civil courts. There, due to our independent judiciary, judges can be impartial towards both parties, prosecution and defense. This is because the Executive branch does not directly influence judges in civil courts.

In addition, without the media present at these trials, no one can truly be sure that the defendants are receiving their due process. Being foreigners, the defendants themselves probably know very little about our legal system, and may not know if they are receiving an unfair trial.

The drafters of the Constitution sought to create a fair and impartial legal system, and they realized *(Continued on page 23)*

BY ANDREW ROSS SILVERMAN

In 1911 Josef Kirzner fled Russia in the hull of the *George Washington* for America in order to escape the political violence that would eventually become the Bolshevik Revolution. Years later, Mr. Kirzner showed the scars on his belly left by the Cossacks' whips. Mr. Kirzner, my great grandfather, embodied the desire for people to live in a society not repressed by control of the press and judiciary.

For over 200 years the Constitution of the United States has protected judicial independence and the free press. Ideally, freedom of press enables people to express what they believe needs to be changed in government, while judicial independence allows a government to change according to the free will of the people.

The framers of the Constitution predicted that other branches of government could compromise the opinions of the judicial branch. The institutional independence of the courts prevents other branches of government from gaining excessive power over the people. For example, Supreme Court Justices are appointed and retain their position for life, only subject to dismissal upon inappropriate behavior, so that they are free to make decisions based on their interpretation of the law and without fear of the consequences of political and other social pressures.

Another example relates to the decisional independence of the Justices. More tenured Justices on the Supreme Court issue opinions subsequent to their juniors, thereby reducing the possibility of inadvertently swaying the opinions of their more recently appointed counterparts. This allows a judge to produce the most pure decisions based on what the law means to him or her. Consistent decisions based on the law provide fair justice for Americans.

Like an independent system of justice, freedom of the press is an equally significant guarantor of a democratic government. Thomas Jefferson once made an *(Continued on page 23)*

Today is the Age of the Specialist

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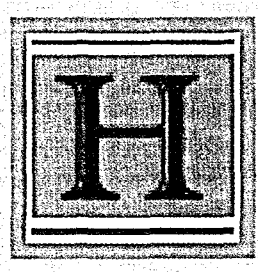

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