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Senate Approves Dr. Margaret Hamburg to Head the FDA

On May 18, 2009, the Senate unanimously approved the nomination of Margaret Hamburg, M.D., to head the Food and Drug Administration (FDA). The FDA regulates products that account for nearly $1 trillion of consumer spending per year. The FDA has an annual budget of almost $2 billion, and 11,000 employees.

Department of Health and Human Services Secretary Kathleen Sebelius called Dr. Hamburg "an inspiring public health leader with broad experience in infectious disease, bioterrorism, and health policy."

The FDA has faced recent criticism over its handling of food contamination and the recall of heparin and Vioxx due to safety concerns. The FDA will also face the challenge of addressing the H1N1 "swine flu" virus. Senator Mike Enzi (R-WY) highlighted the challenges confronting Dr. Hamburg, saying, "she will face unprecedented challenges to public health, from medical product development and biopreparedness to import safety."

During her testimony, Dr. Hamburg discussed several priorities, including addressing H1N1 influenza, improving food safety, and leading an agency that must appropriately balance innovation with regulation.

According to the FDA, Dr. Hamburg is a recognized leader in public health and medicine. She served as the Nuclear Threat Initiative's founding Vice President for the Biological Program. She

also served for six years as the Commissioner of Health for the City of New York and as the Assistant Director of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

FDA Issues Draft Marketing Guidance for Presenting Drug and Device Risk Information

On May 26, 2009, the FDA issued draft guidance for the pharmaceutical and medical device industries, entitled "Presenting Risk Information in Prescription Drug and Medical Device Promotion" (the "Guidance"). The Guidance addresses how risk information should be presented when promoting prescription drugs and medical devices to consumers and healthcare professionals, whether through promotional labeling or advertising. The most frequently cited violation in advertising and promotion enforcement letters is the "omission or minimization of risk information." While the Guidance does not provide any additional rights or responsibilities, once it is finalized it will represent the FDA's thinking on the topic.

The Guidance applies to promotional materials aimed at both consumers and healthcare professionals, and provides many recommendations to help the pharmaceutical and medical device industries appropriately disclose risk information. Under the Federal Food, Drug, and Cosmetic Act, drug and medical device promotional pieces cannot be false or misleading in "any particular," must reveal material facts about the product (including consequences of use), and should give balanced information about the product's effectiveness and risk. When reviewing promotional materials, the FDA assesses the specific statements relating to risk, as well as the "net impression" of a promotional communication to determine whether it is misleading. Although the parts may be accurate, a promotion may be deceptive when taken as a whole, and when the misleading communication causes the product to be misbranded. The FDA confirms that it will use the "reasonable consumer standard" to evaluate promotional materials, and notes that there may be many reasonable interpretations. If one interpretation is false, sellers are liable for that misleading interpretation.

The FDA outlined a number of factors it will consider when reviewing risk communications, covering both the format and content. The FDA relies on numerous studies of human cognition, and the Guidance provides many specific recommendations on how information should be effectively communicated. For example, risk information should be integrated throughout the message, and specific content may vary depending on the length of a piece, the target audience, and the benefit claims that are being made. Material risk information must always be included regardless of the length of a piece or the existing balance of risk and benefit information, and any claim of efficacy generally requires a discussion of a product's most serious risks. Additionally, the Guidance discusses formatting details such as visual displays and contrast, audio volume, dialogue pacing and articulation, and the use of background music. Manufacturers must be careful to ensure that a promotion is not misleading in any way, and any promotion should provide an accurate overall view of the product's relevant properties.

Interested parties may comment on the Guidance at any time, but to ensure consideration before the FDA begins work on the final version, comments must be submitted by August 25, 2009. Be

sure to identify comments with Docket No. FDA-2008-D-0253 from the May 27, 2009 Federal Register Notice. The address for submissions can be found in the Guidance.

President Obama Reverses Former Administration's Policy on Preemption

On May 20, 2009, President Obama issued a memorandum addressing States' rights in relation to the federal government, marking a significant departure from former President Bush's policy. Pursuant to President Obama's memorandum, it will become harder for Federal regulations to trump State laws. As the memorandum is not limited to any particular agency or department, it will affect many industries, including pharmaceutical companies.

In his memorandum, President Obama announced that one of the objectives of his administration is to move back to a general rule that "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the State and with a sufficient legal basis for preemption." To achieve this goal, President Obama outlined the following three steps:

- all department and agency heads need to justify the need for such preemption language before considering it in any new regulations;
- if the determination is made to include preemption language, it must be included in the body of such regulations, rather than in the preamble (as had become common under President Bush's administration), thus giving the public an opportunity to comment upon the proposed preemption language; and
- all heads must look back at the regulations issued by their respective department or agency in the last 10 years to evaluate whether preemption language contained therein (if applicable) meets the standards set forth above, and to take such action as may be appropriate, including amendment of such regulations to assure these standards are met.

The implications of this memorandum are far-reaching and the scope of its impact is not yet known. In the healthcare arena, this is expected to have a significant impact on many of the regulations issued by the FDA, such as the language inserted in the preamble to the 2006 regulations governing drug labels (21 C.F.R. §201 et seq.), which allows for the preemption of certain States' laws, provided manufacturers have complied with FDA labeling guidelines.

President Obama's memorandum does not apply to medical device makers who, pursuant to the Medical Device Amendments of 1976, are protected from lawsuits provided that their products have received FDA approval and comply with all specifications, a view upheld by the United States Supreme Court as recently as last year. However, it is likely that this memorandum will give additional support to the proposed Medical Device Safety Act, which includes language that will prohibit FDA regulations from limiting consumers' rights to seek damages under State law for product liability.

CMS Issues Draft Revised Marketing Guidelines

Medicare Advantage (MA) Organizations and Part D Plan Sponsors had until June 1 to provide comments to the revised Medicare Marketing Guidelines (Draft Guidelines) issued by the Centers for Medicare & Medicaid Services (CMS) late on May 18, 2009. As MA Organizations and Part D Plan Sponsors are aware, the marketing of MA and Part D plans has received much attention over the past year from both Congress and CMS. The Draft Guidelines update the current Guidelines, and incorporate and expand upon the requirements established in the final MIPPA regulations published in September 2008. (73 Fed. Reg. 54208, 73 Fed. Reg. 54226).

CMS asserts that "marketing" extends beyond the general concept of advertising material. Marketing includes any information that promotes the plan sponsor, informs beneficiaries about enrollment in a plan, or explains a plan's benefits or rules. Whether or not someone is directly or indirectly compensated by a plan for marketing activities is not necessarily indicative of whether or not an activity is considered to be marketing under the Draft Guidelines. Although the Draft Guidelines do not implement any new broad policy changes with respect to MA and Part D marketing, they do provide additional detail as to how MA and Part D Plans may market their products and services in compliance with regulatory requirements. Some examples of the clarifications contained in the 177-page document include:

- **Prohibition on Meals:** Plan sponsors are prohibited by regulation from providing meals at any event or meetings where plan benefits are being discussed or materials are being distributed. However, sponsors may provide refreshments and light snacks at such events, and are expected to use their "best judgment" in determining the appropriateness of the food provided. Meals are permitted at educational events, where no sales activities may take place.
- **Telemarketing:** CMS reiterates that sponsors (and their agents and brokers) are prohibited from engaging in direct, unsolicited contact with potential enrollees, including unsolicited calls, and provides additional guidance on telephonic contact, including an explicit prohibition on referrals of beneficiaries and/or their contact information that result in an unsolicited contact. A referred beneficiary must call the plan or agent directly.
- **Marketing in Healthcare Settings:** Plans may not conduct sales presentations and other types of marketing activities "in areas where patients primarily intend to receive healthcare services," including but not limited to waiting and exam rooms, hospital patient rooms, dialysis centers, and pharmacy counter areas where patients interact with pharmacy providers.
- **Adequate Description of Plan Rules and Disclaimers:** The Draft Guidelines expand on the requirements set forth in regulations to place expectations on what is an "adequate" written description of the rules, limitations, procedures, basic benefits and services, and fees and other charges. The Draft Guidelines also require certain statements and disclaimers to be included in marketing materials, such as disclaimers for the marketing of educational events, disclaimers when benefits are mentioned, disclaimers on advertisements and invitations to sales/marketing events, and disclaimers applicable to explanatory marketing.

CMS announced that it will separately issue technical and procedural clarifications regarding CMS marketing models for contract year 2010.

Implementation Plan for HIT under the American Recovery and Reinvestment Act

The Office of the National Coordinator for Health Information Technology (ONC) recently published its plan to implement health information technology (HIT) initiatives mandated under the American Recovery and Reinvestment Act (ARRA). This implementation plan outlines the actions that ONC, in conjunction with the U.S. Department of Health and Human Services (HHS), CMS, the Office of Civil Rights (OCR), and other government agencies will take to facilitate the adoption of HIT by the healthcare industry. Overall, ONC will spend approximately $48 billion to create a national HIT structure, of which $2 billion will be allocated to meet the initial statutory requirements for HIT expansion under ARRA.

ONC and HHS are spearheading the following activities to advance HIT development and adoption:

- expanding HIPAA's Privacy and Security Rules through new regulations that will enhance the enforcement abilities of OCR and CMS and extend certain provisions of the Privacy and Security Rules to business associates;
- funding the development of a healthcare information integration structure and the establishment of a conformance testing infrastructure by the National Institute of Standards and Technology, a non-regulatory Department of Commerce agency with expertise in developing information technology services;
- adopting and publishing an initial set of standards, implementation specifications and certification criteria for HIT;
- engaging governmental and private sector stakeholders to review and provide feedback on the HIT implementation strategic plan;
- defining "meaningful use" of an electronic health record (EHR), as required under ARRA, to authorize incentive payments for hospitals and eligible professionals and ensure that EHRs will be used in a meaningful way. HHS will develop progress milestones and establish delivery dates for the development of this definition; and
- establishing mechanisms for communicating progress about the development of HIT initiatives to the general public.

Medicare and Medicaid HIT Incentives and Administration

The Medicare and Medicaid HIT provisions in ARRA authorize ONC to promote and provide incentives for the adoption of certified EHRs. ONC's plan contained a funding schedule for implementing the Medicare and Medicaid bonus payment structure and administration, and a description of planned administrative activities that will include the establishment of oversight and evaluation procedures for these incentive programs. From the $48 billion allocated for HIT implementation under ARRA, ONC and CMS collectively will spend approximately $46 billion to implement and oversee the Medicare and Medicaid incentive structures through fiscal year 2019.

Throughout its fiscal year 2009, CMS will use implementation funds to begin to realize specific statutory requirements, which will include:

- coordinating with ONC to develop the "meaningful use" of EHR definition;

- developing and publishing proposed regulations related to the Medicare and Medicaid incentive programs;
- establishing payment policies under the Medicare and Medicaid incentive programs and mechanisms to assess these policies;
- planning and providing healthcare provider outreach on the incentive plans and imposing Medicare penalties for not adopting meaningful use of EHRs; and
- providing technical assistance to support state outreach and education programs.

Subsequent implementation plan activities will expand upon CMS's 2009 tasks. More specifically, CMS will focus on developing education and provider outreach programs, providing contractor support, and assessing and evaluating the incentive programs and the providers that adopt certified EHRs.

ONC's implementation plan, including useful reference timelines for accelerating the adoption of HIT by the healthcare industry, and a complete description of the Medicare and Medicaid incentives and administrative funding scheme are available on the HHS website. The plan also identifies certain factors that may alter the implementation schedule, including the need for ONC to develop and finalize the EHR certification criteria and define "meaningful use."

OIG's Recent Advice Focuses on Arrangements Involving Financially Needy Patients

Over the last few weeks, the Office of Inspector General (OIG) issued two Advisory Opinions and modified an earlier Advisory opinion. All three guidance documents effectively supported programs that aim to increase access to care and reduce co-payment obligations for financially needy individuals.

Advisory Opinion 09-04, issued on May 11, 2009, involved a program operated by an independent, non-profit organization that provides financial assistance to needy patients by covering their cost-sharing obligations for certain advanced diagnostic testing related to either HIV or colorectal cancer. The charitable organization receives donations from entities, including drug manufacturers, pharmacies, and service providers. The OIG approved the program, finding that it included many safeguards that preserve patient freedom of choice and that promote and maintain the independence of the charitable organization.

In its Advisory Opinion 09-05, issued May 14, 2009, the OIG evaluated a hospital's proposed program to compensate physicians who provide on-call services for uninsured patients who present to the hospital's emergency room. Under the proposal, active medical staff who provide on-call coverage and agree to certain policies will be able to submit claims to the hospital for certain care provided to uninsured patients who present to the emergency room. In this Advisory Opinion, the OIG recognized that compensating physicians for on-call services can create significant fraud and abuse risk but concluded that it is possible to structure such programs to greatly reduce risks by attempting to develop arrangements that comply or nearly comply with the personal services safe harbor under the Federal Anti-kickback Statute. Ultimately, the OIG approved the hospital's proposal, finding that the arrangement presented a low risk of fraud and

abuse because it met many, but not all, of the elements of the safe harbor, the hospital revised its program for a legitimate reason, and the program would be offered uniformly to all physicians.

Finally, on May 19, 2009, the OIG modified Advisory Opinion 08-11, originally issued in September 2008, by expanding the list of providers, practitioners and suppliers permitted to waive Medicare cost-sharing obligations in connection with a particular clinical trial by the National Heart, Lung and Blood Institute and CMS.

House and Senate Republicans Unveil Comprehensive Healthcare Reform Proposals

Congressional Republicans have started rolling out comprehensive healthcare reform legislation to counterbalance Democratic reform bills currently pending in the House and Senate. On May 20, a group of Republican House and Senate members, led by Representative Paul Ryan (R-WI) and Senator Tom Coburn (R-OK), introduced the Patients' Choice Act (PCA) (H.R. 2520, S. 1099), which would expand health insurance coverage through a combination of tax credits and state-level insurance exchanges while limiting government involvement in healthcare decisions. The PCA stands in contrast to healthcare reform proposals favored by the Obama administration and Congressional Democrats because it does not include an individual mandate to purchase insurance or a new public insurance option.

The PCA places greater emphasis on commercial insurers in an effort to transition away from publicly funded entitlement programs. The PCA's primary features are tax credits to qualified individuals to purchase insurance from a private health plan and state insurance exchanges to foster individual enrollment. The PCA's proponents projected the proposal to be budget-neutral and highlighted the PCA's cost-saving elements, which the proponents advised will reign in the skyrocketing cost of healthcare treatment and insurance coverage in the long term and will encourage private insurers' participation in the insurance exchanges. One example is the PCA's focus on preventive medicine. Rather than paying to treat the illness after the fact, the PCA includes mechanisms to better manage and prevent chronic disease and to encourage individuals to adopt healthier lifestyles and behaviors. The net effect, according to the sponsors, will be lower private insurance premiums and decreased Medicare and Medicaid expenditures.

On the tax side, the PCA would replace the current employee income tax exclusion on employer-provided healthcare benefits with advanceable and refundable tax credits to qualified individuals to purchase health insurance. The tax credits would amount to approximately $2,300 per individual and $5,700 for each family. Qualified individuals include those who are eligible for Medicaid and State Children's Health Insurance Program benefits. Any credit allotment above the cost of health insurance would be deposited into a medical savings account that may be used to cover additional medical expenses. Employer contributions toward employee healthcare would still be deductible as a business expense, and individuals may elect to retain their current employer-sponsored coverage.

The PCA also would increase the monthly contribution limits for health savings accounts (HSAs) to $3,000 per individual and $5,950 for each family. Employers could further

supplement their employees' HSA contributions to assist employees with chronic diseases. Additionally, the PCA would expand the permitted uses of HSA funds to include health insurance premiums, over-the-counter medications, dental and vision care, preventive services, and concierge-style primary care services.

The state-based insurance exchanges would guarantee consumer access to private health insurance plans and would provide consumers the opportunity to compare and contrast participating plans and base purchase decisions on price and quality of coverage. These exchanges would promote enrollment through an auto-enrollment mechanism available via employers, hospitals, state DMVs, and similar venues. Individuals would have the opportunity to opt out of participation.

While not required to participate, those insurance plans that elect to take part in the exchanges would need to meet several criteria. For example, participating insurers would need to offer benefits providing at least the same standard health benefits available to members of Congress. Plans also would be prohibited from discriminating based on age, existing conditions, or prior medical history. To discourage cherry-picking among the healthiest consumers, the exchanges would keep premiums low through risk adjustment procedures, health security pools, reinsurance mechanisms, or other measures.

Given the strong Democratic majorities in both Congressional chambers and a Democrat in the White House, the chance for passage of any Republican healthcare reform proposal is unrealistic. Rather, Congressional Republicans are likely to offer all or select portions of bills like the PCA as amendments to Democratic-sponsored bills, either during committee markups or floor debate. Regardless of the forum, the pending Congressional debate promises to be lively. Stay tuned…

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