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In the News

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BLUES' TESTIMONY ANGERS MEMBERS OF LASAGNA COMMITTEE

Testimony by a representative of the National Blue Cross and Blue Shield Association that Treatment IND and NCI Group C drugs are "investigational because their efficacy has not been demonstrated sufficiently to warrant full FDA approval to market," angered members of the Lasagna Subcommittee of the President's Cancer Panel.

David Tennenbaum of the Blues testified that coverage of such treatments would be "inconsistent with our principle of coverage for effective treatment," which includes "conclusive scientific evidence that use of a technology improves health outcomes."

Committee member Samuel Hellman, M.D., Dean of Biological Sciences, Pritzker School of Medicine, the University of Chicago, said, "Medicine has never been practiced by moving forward with 'conclusive' medical evidence. It just doesn't work that way." Peter Hutt, Partner, Covington and Burling, Washington, DC, added that "FDA approval has never been based on conclusive scientific evidence. It is based on what is called 'substantial' evidence, which, under the legislative history, may be less than 50 percent of the evidence. Even FDA has never believed that one must have conclusive evidence."

Hellman suggested that insurance companies' efforts to cut costs were being hidden "under the guise of protecting patients from uncertain therapy." He questioned Tennenbaum's assertion that costs are not a consideration in the evaluation of new technology. "Then what is it, if it isn't cost?" he asked. "Do you think you know better than the physicians or the medical community as to efficacy?" And Committee Chairman, Louis Lasagna, M.D., Dean, Sackler School of Graduate Biomedical Sciences, Tufts University, asked Tennenbaum if he was saying that "the NCI, the FDA, and HCFA with their collective wisdom have [not] made the right judgment?"

Tennebaum replied, "We certainly want to know what HCFA's policies are in terms of administering Medicare, but for our own private business, we do make our own decisions."

> ***"There is no rational explanation you can give to a Duke's C colon cancer patient why Medicare will reimburse [for Group C drugs] and Blue Cross/Blue Shield won't"***

Samuel Broder, M.D., NCI Director and a spectator at the meeting, took "vigorous and strong exception to the opinion that Group C drugs are investigational." He pointed to the success of levamisole and 5FU for the treatment of colon cancer, saying, "there is no rational explanation you can give to a Duke's C colon cancer patient why Medicare will reimburse [for Group C drugs] and Blue Cross/Blue Shield won't."

Hutt said that by taking such a position, "the most effective treatment available will not be reimbursed." He also expressed concern about variances in coverage policies between local Blue Cross/Blue Shield plans, noting that "a drug might be [labeled] effective in San Francisco and ineffective in Toledo."

Lee Mortensen, ACCC Executive Director, testified that increased denials by insurers were "leading oncologists away from the use of agents they believe are more effective for their patients." While Tennebaum testified that "possibly" the three compendia might be used in examining payment for off-label indications, Mortenson said he would "insist upon it as a minimum." Mortenson also suggested that "use of the three compendia for Medicare Part B, federal employees, CHAMPUS, federally-sponsored HMOs, and for military employees and dependents could be mandated by the President," and would serve as "an important example" to other insurers.

When Mortenson was questioned by Hutt about his views on the formation of a national commission to recommend payment for new indications of approved drugs and new investigational agents, he said he would approve of such a commission only if "rapid review [of new agents] is ensured, the three compendia are used as the starting point for determining coverage, and insurance companies buy into the commission's recommendations."

HIAA RELEASES PAYMENT GUIDELINES FOR UNAPPROVED DRUGS

A task force of the Health Insurance Association of America (HIAA) recently outlined a series of guidelines that offer a framework for identifying issues and concerns to be addressed in weighing coverage of unapproved drugs, according to testimony by David Plocher, M.D., Vice President for Medical Services, the Prudential Insurance Company of America, before the Lasagna Committee.

The task force, which was composed of medical directors from 12 major member companies of HIAA, has recommended considerably more flexibility in payment for unapproved drugs and drug-related costs than Blue Cross and Blue Shield currently endorses.

For example, Plocher told Committee members that, in the case of off-label use of drugs, the guidelines recommend that insurers "rely on the three compendia" (the AMA's *Drug Information*, the *US PDI*, and the *AHFS Drug Information*). Plocher also said that the use of investigational drugs for "immediately life-threatening conditions in FDA-sanctioned clinical trials, under Treatment INDs, and in NCI Group C, should not be a reason to exclude coverage if evidence from literature and clinical trials supports their use. (For more information on the guidelines, see the sidebar "How the HIAA and the Blues Match Up" on the next page.)

It is uncertain, however, if members of HIAA will accept the task force's recommendations. At *Oncology Issues* deadline, Jude Payne, Senior Policy Analyst, HIAA, said that copies of the guidelines were still being printed for the 320

member companies. And representatives of Prudential and John Hancock told *Oncology Issues* that coverage decisions will not be made until the guidelines are received and reviewed by management. To date, Payne says HIAA has received comments ranging from "obvious support" to criticisms that the recommendations are "too generous." However, she points out that the medical directors on the task force, who represent present medical practice and have input in company policymaking, are "obviously supportive of the guidelines."

How the HIAA and the Blues Match Up

COVERAGE ISSUE	HIAA	BLUES
Off-Label Use	Consult the three compendia and peer-reviewed literature	Do not categorically exclude; Compendia one "possible" source
Orphan Drugs	Same criteria as off-label	Until NDA is filed and and approved, considered investigational and excluded from coverage
Treatment IND and NCI Group C Drugs	Evaluate each individual agent for coverage	Excluded from coverage
Investigational Drug in a 3- to 4-Drug Regimen	Consider coverage for hospital stay; exclude coverage for cost of experimental agent	No national policy on combination therapy that includes an experimental agent; coverage decided at local level
Monotherapy With An Unapproved Drug	Exclude cost of hospital stay unless patient would require hospitalization regardless of drug treatment	Excluded from coverage
Complications Resulting From the Use of An Unapproved Drug	Unexpected complications should be covered; expected complications excluded from coverage	Excluded from coverage

FDA'S EXPEDITED REVIEW PROCESS RAISES INDUSTRY FINANCING, PAYMENT CONCERNS

The Food & Drug Administration's proposed rule for expedited approval of drugs for life-threatening and severely debilitating diseases may prove to be a crippling blow to small biotechnology firms with limited resources, according to speakers at a joint American Medical Association/ FDA conference on drug regulation and availability in Vienna, VA.

Panelist Nancy Buc, Partner, Weil, Gotshall and Manges, was skeptical of small biotechnology firms' ability to make the type of "full court press" that Bristol-Myers did when its HIV agent, DDI, was approved by the FDA as a Treatment IND and for expanded access under a Compassionate IND. Because of limited resources, Buc questioned whether or not smaller firms can "afford Treatment IND."

Lester Soyka, M.D., Vice President, Clinical Development, Bristol-Myers Co., said that the "real world impact of expedited development of DDI" necessitated additional staffing, equipment, and significant increases in demand on other company resources. For instance, the company received more than 10,000 phone calls about DDI's availability and, at the time of the conference, 314 patients had been enrolled under the care of 170 physicians.

How widespread is the potential impact of expedited review on small biotechnology and pharmaceutical firms? The Center for Biologics at FDA estimates that approximately 120 biological-related INDs are eligible for expedited processing, according to Gerald Quinnan, M.D., Deputy Director of the Center. And, with regard to pharmaceuticals, the FDA has identified 96 INDs as candidates for expedited process, and another two dozen candidates in the AIDS and cancer areas, said Joseph Levitt, Director of FDA's Office of Executive Operations.

Speakers also had safety concerns about expedited drug review. FDA's proposed new rule "changes the risk-benefit threshold for companies," Daniel Hoth, M.D., Director, AIDS Program, NIAIA, pointed out. He stressed the need for "clinical investigators to be involved in dialogues between FDA and industry."

He was also critical of investigators for placing "too much reliance on FDA" and generating "too little discussion among themselves." Investigators should be "advising FDA about thresholds for distributing new drugs," he contended. And, predicting a "significant increase in the number of drugs being developed, especially for AIDS," the role of community physicians will be increasingly important," Hoth maintained, "not only in the execution of trials, but in their design."

The FDA plans to play a "more proactive role in drug development," FDA's Levitt said. To that end, the Agency plans to consult with companies and investigators before phase I trials on the content of animal studies, and at the end of phase I trials to discuss the structure of phase II controlled trials. The FDA also plans to perform "phase IV postmarketing studies on risk, benefit, and optimal use," Levitt explained.

Edward Langson, M.D., Director, Family Practice, Community Hospital, Indianapolis, IN, praised the FDA for its

"wisdom" in instituting postmarketing surveillance, stressing its importance in an "expedited system, particularly for cancer and AIDS drugs." But Lawrence Friedman, M.D., Association Director, Clinical Research and Prevention Program, NHLBI, predicted that "without consensus over surrogate endpoints," FDA's "preconferences won't have much impact." He also charged that "the need to direct resources to evaluate surrogate endpoints is not being adequately addressed." And Donald Abrams, M.D., Assistant Director, AIDS Activities, San Francisco (CA) General Hospital, cautioned that FDA's so-called "activism" could also be viewed as "obstructionism." He questioned whether, in some cases, FDA could have "too much input in clinical trials."

But the greatest concern speakers expressed over expedited review and expanded access to new drugs and biologicals involved cost and payment issues. Mark Harrington, Treatment and Data Committee, AIDS Coalition to Unleash Power (ACT UP), pointed out that despite the FDA's "new willingness to work with the AIDS community" in making new therapies available, in many cases "the health care financing industry is not willing to pay for those therapies. Health care financing is not keeping pace with research innovation by the pharmaceutical industry and NIH," he contended.

Abrams criticized the lack of an insurance industry representative on the FDA's parallel track committee as a "serious shortcoming." Hoth of NIAID shared Abrams' conviction that the insurance industry must be involved, warning that its support is "essential" to the ultimate health of clinical trials. "The nation only spends about three percent of the national budget on research and development in medicine." But this is an issue, Hoth pointed out, that "we have never requested the insurance industry commission to take a stand on or to explore."

One of the keys to "understanding and negotiating reimbursement relief" is to "find a way to price products and to work collaboratively," said Grace Monaco, Chairman of the Board, Candlelighters Children's Cancer Foundation. "That means we can't pay for ineffective or overpriced care." A more troubling, semantic issue, according to Monaco, is being able to distinguish between patient "want" and patient "need."

> *"After public-supported research leads to new treatments, the public that subsidized that research is not able to receive the treatment"*

Harrington of ACT UP condemned the fact that "after public-supported research leads to new treatments, the public that subsidized that research is not able to receive the treatment. Only the affluent can afford AIDS treatment." As a result of the current "patchwork" of national coverage policy and of federal government and insurance industry actions that "fail to go far enough," Harrington predicted a "restructuring" of the entire health care system. "Patients as partners with physicians in making treatment decisions is an idea whose time has come, and which will reshape the landscape of health care," he said. And, he added, "community research has a key role to play" in that restructuring.

LACK OF STAFF, SPACE PROLONGS FDA'S DRUG REVIEW PROCESS

Two hundred additional drug reviewers, once they were fully trained, would reduce the current 24 months it takes FDA to approve a new drug application to 12 months, said Frank Young, then FDA Commissioner, in testimony before the National Committee To Review Current Procedures For Approval Of New Drugs For Cancer And AIDS. The Committee, chaired by Louis Lasagna, M.D., was told that the most pressing problem was a lack of space. Carl Peck, M.D., Director of the Center for Drug Evaluation and Research, said that "up to 50 approved FTE positions remain unfilled because of the lack of space."

A General Accounting Office (GAO) report on FDA resources, including staffing, facilities, and equipment needs recommends that Congress require "the FDA Commissioner to conduct an agencywide assessment to identify and prioritize its activities and responsibilities." Mark Nadel, Ph.D., Associate Director, National Public Health Issues, GAO, told the Committee that, in specific, the report says that the FDA should 1) assess its

NTRA Publishes New Desk Reference

A new desk reference that provides detailed information on oncology-related organizations and publications is now available from the National Tumor Registrars Association (NTRA). The publication, *Tumor Registry Desk Reference: Volume I, Directory of Oncology-Related Organizations and Publications—1989*, is intended to serve the needs of cancer registration professionals, physicians, and organizations involved in cancer care.

The volume profiles 90 cancer-related organizations, 130 standard reference books, and 120 cancer journals and periodicals. The publication also provides information on state cancer reporting laws, central registries, NCI-supported cancer centers, cooperative groups, and cancer registry software vendors.

The volume is available at $25 per copy (postage paid), from NTRA, 505 E. Hawley St., Mundelein, IL 60060. Checks should be made payable to the NTRA. For further information, contact Robert B. Willis (312)949-6050 or April Fritz (916)682-3761.

responsibilities and the staff requirements to meet these responsibilities based on present and future projections, 2) determine the activities it can effectively undertake given a specified level of staffing increases (i.e., 2 percent, 5 percent, etc.), and 3) identify the management changes it would implement to match specific staffing levels with higher priority responsibilities.

Nadel confirmed that FDA staffing levels have declined eight percent between 1980 and 1989, although "Congress has enacted more than a dozen new laws that have increased FDA's responsibilities," such as the orphan Drug Act and the Prescription Drug Marketing Act. In the area of new drug application review, Nadel said FDA maintains that "staffing shortfalls, particularly in the number of medical officers, have delayed its reviews, which are taking about 31 months—five months longer than allowed by law."

According to FDA, it needs more than 2,000 additional positions to replace those lost since 1980, to fully implement new legislative requirements, and to handle responsibilities related to AIDS. However, Nadel testified that the FDA "did not base its staffing estimate on a comprehensive assessment of current and future staffing needs," but on "information compiled from judgmental estimates of senior FDA officials and a variety of center and field office time and activity reporting systems."

Committee Member Charles Leighton, M.D., Senior Vice President, Merck Sharp and Dohme, questioned Nadel about the FDA's ability to prioritize its activities. "My concern," he said, "is not a matter of FDA not knowing its priorities," but of the "pressures it must cope with from outside constituencies." Peter Hutt, Partner, Covington & Burling, agreed, saying, "There is tremendous pressure on FDA to do all kinds of things. who is going to step up to this issue and say what FDA should stop doing?" Nadel replied that the FDA will have to work closely with Congress "to help alleviate outside pressures," as well as to "insulate the FDA from pressures originating from within factions of Congress itself."

NCI PUBLICATIONS AVAILABLE

The National Cancer Institute (NCI) has developed two publications to provide cancer patients with information about clinical trials. The pamphlet, "Cancer Treatments: Consider the Possibilities," and the booklet, "What Are Clinical Trials All About?" are available free of charge.

To order, call 1-800-4-CANCER or write to: Department CT, National Cancer Institute, Building 31, Room 10A24, Bethesda, MD 20892.

CANCER CENTERS EXEMPT FROM STARK BILL

The National Alliance of Outpatient Cancer Therapy Centers has successfully lobbied for the exemption of cancer centers from Rep. Fortney (Pete) Stark's (D-CA) Ethics in Patient Referrals bill.

The final version of the Stark bill, passed by the House and Senate in the Budget Reconciliation Act, applied only to clinical labs and excluded cancer therapy and other therapeutic modalities from the prohibition against physician referrals to facilities in which they own an interest. The Alliance successfully argued that therapeutic modalities did not lend themselves, by the nature of the care they provide, to the kind of fraud, abuse, and over utilization the Stark bill addresses.

At *Oncology Issues* deadline, the Budget Reconciliation Act, the omnibus bill containing physician self-referral provisions, was sent to the White House for the President's signature.

MARYLAND BLUES ELECT TO COVER MAMMOGRAMS

Two Blue Cross plans with policyholders in Maryland, the District of Columbia, and Northern Virginia have expanded their benefits to include routine mammograms. Blue Cross and Blue Shield of Maryland will now cover one preventive screening for women under the age of 40 and one screening per year for women over the age of 40. Blue Cross's National Capital plan will cover one preventive screening for women between the ages of 35 and 39, one screening every two years for women between the ages of 40 and 49, and annual screenings for women over the age of 50.

ASCO APPOINTS REGIONAL REPRESENTATIVES

The American Society of Clinical Oncology's Clinical Practice Committee, has appointed 10 regional representatives to help area oncologists with local coding problems, denials for off-label indications, and other local and regional problems, according to Joseph Bailes, M.D., chairman of the committee.

Information reported to the regional representatives will be used to create a database to address problems with third-party carriers and to facilitate the rapid dissemination of changes in oncology-related CPT codes and their interpretations.

The regional representatives are as follows:

Peter Eisenberg, M.D.
California
415/457-1150

Lloyd Everson, M.D.
Indiana
317/353-5769

Ronald Carroll, M.D.
Maine
207/773-1754

Dale Cowan, M.D.
Ohio
216/662-2059

Robert Enck, M.D.
Ohio
614/764-8178

Lee Newcomber, M.D.
Oklahoma
918/495-1243

Rodger Winn, M.D.
Texas
713/792-6515

HCFA STUDIES ANALYZE COST OF CANCER CARE

It will be another 18 months to two years before the Ambulatory Patient Groups (APGs)—the outpatient equivalent of DRGs—which were developed by the Health Systems International and are being evaluated for the Health Care Financing Administration (HCFA) by researchers at Brandeis University, are ready for commercial use, according to Joanna Lion, PhD, a Research Professor at Brandeis.

Speaking at a workshop on "Minimizing the Economic Impact of Cancer" at the Sixth National Cancer Communications Conference in Washington, DC, Lion presented some preliminary data on hospital outpatient care for cancer patients in the Medicare population. She noted that hospital-based outpatient care for malignancies is the third most costly type of care in terms of total outpatient dollar expenditures by Medicare. Cancer care is exceeded only by cataract surgery and dialysis for chronic renal failure. Preliminary data show that cancer hospital outpatient treatments cost Medicare about $800 million per year, according to Lion.

The majority of 1989 outpatient dollars for cancer treatment were spent on ambulatory surgery procedures ($193.5 million per year or 24 percent of total cancer outpatient expenditures). Chemotherapy administration costs totaled $34.5 million per year for complex chemotherapy, $6.8 million for simple chemotherapy, and $1.4 million for very complex chemotherapy. The study was based on more than 31,000 outpatient visits in 1989. If the cost of routine referred tests are included (estimated at $104 million per year), the total annual cost of cancer care in outpatient departments was $900 million in 1989.

Lion also presented data on mean charges for particular cancer treatments, based on one- and two-week analyses of the universe of Medicare outpatient claims in October 1988. The study found that the most common charges were for a visit without any major diagnostic or therapeutic procedure (25 percent of all visits). The most expensive procedures were the installation of vascular access lines (mean charge of $1,107), radiation therapy set up and continuing consultation (mean charge of $1,071), and the administration of very complex chemotherapy (mean charge of $1,035).

The most common cancers treated on an outpatient basis in the Medicare population in 1989 were prostate, lung, breast, and colon. The highest dollar expenditures by diagnosis, however, ranged from $83.7 million for prostate cancers to $6.2 million for cervical cancers.

Another speaker at the workshop, Gerald F. Riley, Research Analyst, Division of Beneficiary Studies, HCFA, reported on a joint project by HCFA, NCI, and nine cancer registries which is attempting to link cancer registry data to Medicare utilization and cost data. A new data set that matches Medicare patients with patients in the SEER database at NCI and tumor registry records is being developed to enable HCFA to accurately identify the Medicare cancer population, to determine geographic variations in care, to track treatment patterns and the cost of care, and to measure the effect of early detection and prevention on the cost and use of treatment.

To date, the involved registries have been able to match about 80 percent of cancer patient records with Medicare claim information. A preliminary report, based on a national sample of five percent of Medicare beneficiaries and data from the years 1974 through 1985, shows that expenses for cancer treatments are highest in the year of diagnosis (an average of $10,000), followed by the year following diagnosis ($5,000). The analysis tracked cancer patient costs for nine calendar years following diagnosis. Overall, Riley said, costs for cancer treatments in following years average $3,000 to $4,000 per year. compared to average expenses of $2,000 per year for all Medicare beneficiaries (See above table.)

According to Riley, the next step the project will take is to identify specific types of treatments Medicare cancer patients receive (i.e., the cost impact of mammography services), and to monitor trends in cancer care, as well as geographic patterns of care. ■

PRELIMINARY NATIONAL SAMPLE OF MEDICARE CANCER PATIENTS COSTS OF CARE/MORTALITY RATES

	Medicare Expenditures		Mortality Rates	
Type of Cancer	Year of Diagnosis	Following Year	Year of Diagnosis	Following Year
All Cancers	$10,622	$4,993	26.6	26.2
Breast	7,499	3,180	6.5	9.6
Colon	12,613	5,174	20.7	22.1
Prostate	8,497	3,598	11.7	12.7
Lung	12,045	6,801	48.1	60.5

*Expenses in 1985 dollars. Expenditures include Medicare Part A and Part B services. Data based on a total of 10,993 patients. Only the costs for those patients who survived the year of diagnosis are included in the costs for the following year.

Brochure Promotes Prostate Cancer Awareness

A free brochure, "Prostate Cancer: Some Good News Men Can Live With," has been produced to help raise awareness among men of the disease and to emphasize the importance of early detection and screening examinations. The brochure was developed by the Prostate Cancer Education Council, a panel of physicians, health educators and patient support groups, and by the National Cancer Institute.

Free copies can be obtained by calling NCI's toll-free hot line, 1-800-4-CANCER, or by writing to the Prostate Cancer Education Council, JAF Box 888, New York, NY 10116.