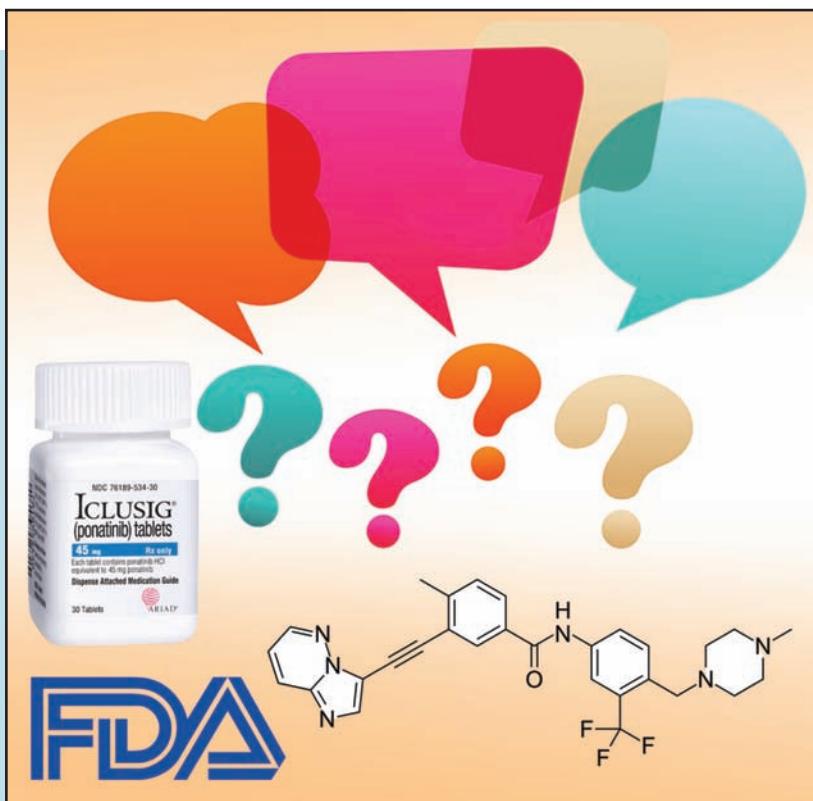


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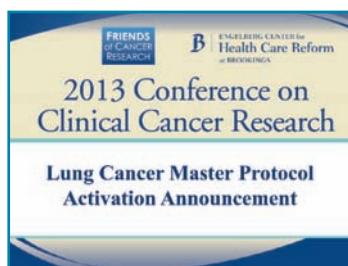


## The Ponatinib Problem: Debating the FDA's Recent Market Suspension

BY SARAH DIGIULIO

**A**lthough promising early results led to the accelerated approval of the leukemia drug, recently reported longer follow-up data showed an increased risk of arterial thrombotic events—prompting the FDA to temporarily suspend marketing and sales of the drug. But, several experts told us that for some patients, the potential benefits may still outweigh the risks.

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Unique Trial Protocol Announced for Lung Cancer

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Novel Agents Rapidly Emerging for CLL

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Central Line Care Bundle Benefits Ambulatory Pediatric Cancer Patients

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# Business Group Releases Employer Guide to Cancer Treatment and Prevention

BY PEGGY EASTMAN

Len Lichtenfeld, MD, of the ACS praised the depth, detail, and practicality of the new employer guide, stating that in the United States “we have a tendency to highlight problems without providing workable solutions. We have to have a way to get there; this work gets there.”

WASHINGTON—Mindful of the increasing burden of cancer in the workplace, the nonprofit National Business Group on Health (NBGH) unveiled a comprehensive blueprint for employers to follow in providing the best cancer care for their employees. “An Employer’s Guide to Cancer Treatment and Prevention” is the business community’s first publication of its kind, said NBGH President and CEO Helen B. Darling, speaking here at a news briefing at the National Press Club.

The new guide, which comes at a time of soaring costs for cancer care, is available in a series of pdfs posted at [businessgrouphealth.org/cancer](http://businessgrouphealth.org/cancer).

The organization represents about 377 employers in mostly large businesses, including Fortune 500 companies. NBGH members collectively provide health care coverage to approximately 50 million U.S. employees and retirees and their family members.

“As an organization, we work on finding solutions to the most serious problems employers face,” Darling said. “Employers care about their employees, and many are living with cancer.”

She noted that for many employers, costs for cancer are among the top three conditions their employee health plans pay for, representing about 12 percent of employee medical expenses. Cancer is the leading cause of long-term disability, totaling 17 percent of all cases; for short-term

disability, cancer averages 93 days of leave. Cancer treatment leads all other diseases in terms of medical and pharmacy costs, she added.

The new guide is intended to help employers provide their employees with the best possible evidence-based cancer care as early as possible—“instead of wandering through the quagmire of the current health care system,” she said.

## Collaboration with NCCN

The guide, which contains a checklist of key benefits, was developed over a three-year period in collaboration with the National Comprehensive Cancer Network (NCCN). The blueprint is the product of a multi-disciplinary 35-member advisory committee representing clinical cancer

that will help cancer patients, caregivers, and their loved ones. He noted that the NCCN guidelines are widely known, and because the new employer blueprint represents a collaboration with NCCN, the contents are “closely aligned with the mission of our organization.”

“As a practicing hematologist, I can attest that this guide will have a profound impact on patients,” said Samuel M. Silver, MD, PhD, MACP, Assistant Dean for Research at the University of Michigan Medical School; Chair of NCCN’s Board of Directors; a member of the new guide’s advisory committee; and a cancer survivor.

Silver, who said the new employer guide “has been one of the most innovative and influential projects I’ve been



care, academia, industry, benefit managers, disability managers, employee assistance professionals, and consultants. Included is specific, detailed guidance on how to define, structure, and implement evidence-based cancer benefits, programs and services in health plans for employees, including the costs of implementing the recommendations.

Also speaking at the briefing, NCCN CEO Robert W. Carlson, MD, called the guide “a unique and valuable tool”

involved with,” cited the guide’s recommendations on specific, needed benefits for cancer patients, including coverage of a second opinion; coverage for fertility-preservation counseling; and coverage for genetic counseling. He said he expects the guide’s “strong framework” to have a wide impact in the public as well as the private sector.

In addition to providing recommendations on cancer care, the guide also provides strategies for cancer prevention, noted another member of the guide’s advisory committee, Lynn Zonakis, RN, Managing Director for Health Strategy &

## Specific Recommendations

Among the guide’s recommendations are the following:

1. An employee’s benefit plan should include access to a Center of Excellence program for transplants, including bone marrow and stem cell transplants, and for employees with aggressive, complex, and rare cancers. The plan should cover travel and lodging assistance for these employees.
2. Reasonable out-of-pocket pharmacy thresholds should be established so that drug costs are not a barrier to cancer patients, and employers should ensure that their plans cover evidence-based cancer treatments. This includes coverage for off-label use of drugs and biologics when supported by scientific evidence accepted by the NCCN and ASCO.
3. The plan should cover the routine costs of care when the patient is enrolled in an approved cancer clinical trial – at the same level as coverage for comparable services when an employee is not in a clinical trial.
4. The plan should include hospice coverage for patients with an estimated life expectancy of 12 months or less, with up to five days of inpatient respite care per three-month period (to relieve the primary caregiver).
5. Physicians should be reimbursed for consultations with patients and family members about their care options, including palliative care and hospice.
6. The benefit plan should cover screening for depression and other behavioral health conditions.
7. The benefit plan should include coverage for molecular or biomarker testing and genetic counseling based on NCCN clinical practice guidelines.
8. Employers should contract for case management services and require that oncology nurses be available to work with patients.

“As a practicing hematologist, I can attest that this guide will have a profound impact on patients.”

—Samuel M. Silver, MD, PhD, MACP

Resources for Delta Airlines. “Many cancers are preventable or more effectively managed if identified early. There is a prevention and education opportunity; the workplace provides a unique opportunity to effectively communicate.”

She added, “With an average age of 48 [at Delta], we’re going to see a lot of cancer . . . One of our focuses has been on prevention.” Zonakis noted that Delta provides 100 percent coverage for recommended cancer screenings, a policy that has been in place for many years.

*continued on page 13*

# FDA Approves Another Thyroid Cancer Indication for Nexavar (Sorafenib)



The U.S. Food and Drug Administration has expanded the approved uses of Nexavar (sorafenib) to treat late-stage, metastatic differentiated thyroid cancer. The drug works by inhibiting multiple proteins in cancer cells to limit their growth and division. The drug's new use is intended for patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

"Differentiated thyroid cancer can be challenging to treat, especially when unresponsive to conventional therapies," Richard Pazdur, MD, Director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research, said in a news release. "This approval demonstrates the FDA's commitment to expediting the availability of treatment options for patients with difficult-to-treat diseases."

The FDA completed its review of Nexavar's new indication under its priority review program, which provides for an expedited, six-month review for drugs that may offer a significant improvement in safety or effectiveness of the treatment, prevention or diagnosis of a serious condition (*OT 9/25/13*). Nexavar also received Orphan Product Designation by the FDA because it is intended to treat a rare disease or condition. Approximately 60,220 Americans will have been diagnosed with the disease this year, according to National Cancer Institute estimates.

Safety and effectiveness were established in a clinical study of 417 patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that was not responding to radioactive iodine treatment. Nexavar was shown to increase progression-free survival by 41 percent: Half of the patients receiving Nexavar had

progression-free survival of 10.8 months compared with 5.8 months for patients receiving a placebo.

The most common side effects associated with the drug were diarrhea, fatigue, infection, alopecia, hand-foot skin reaction, rash, weight loss, decreased appetite, nausea, gastrointestinal and abdominal pains, and hypertension. It was also noted that thyroid-stimulating hormone, a potential promoter of thyroid cancer, is more likely to become elevated while patients are on treatment with Nexavar, requiring adjustment of thyroid hormone replacement therapy.

Nexavar was approved to treat advanced kidney cancer in 2005 (*OT 2/25/06*), and the FDA expanded the drug's label to treat liver cancer that cannot be surgically removed in 2007.

Nexavar is co-marketed by Bayer HealthCare Pharmaceuticals Inc. and Onyx Pharmaceuticals. ☐

## →EMPLOYER GUIDE

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Asked by *OT* about the new employer guide's generous recommendations on hospice care for patients with a life expectancy of up to 12 months, both Silver and Zonakis agreed that hospice is a vastly underused resource that can be of great help and comfort to patients with advanced cancer and their families. Silver said fear of abandonment by their oncologist is one barrier to cancer patients' acceptance of hospice.

He said that rather having an abrupt care transition, which the patient can perceive as "goodbye, I'm handing you over," he advised introducing a team of symptom management and palliative care specialists early in treatment. This continuum-of-care approach, which stays in place, allows earlier acceptance of hospice on the part of the cancer patient should it become the best choice, he said.

Darling advised that every hospital an employer contracts with should be certified in palliative care.

### 'Pleasantly Surprised'

In an interview, J. Leonard Lichtenfeld, MD, MACP, Deputy Chief Medical Officer of the American Cancer Society and a member of the new guide's advisory committee, said he was "pleasantly surprised" at how willing the corporate community was to support and advance the highest-quality, evidence-based cancer care. In sitting around the table with business representatives, he said, their attitude was "If the evidence supports the recommendation, this is something we should do."

Recommendations stating that palliative care is part of the treatment continuum are forward thinking, he said: "That's

a huge transition from where we were just a few years ago."

Lichtenfeld praised the depth, detail, and practicality of the new employer guide, stating that in the United States "we have a tendency to highlight problems without providing workable solutions. We have to have a way to get there; this work gets there.

"We really need to look carefully at how care is delivered in this country," and the new guide provides a structured framework for doing that. "Hopefully it will be

well received in the employer world," he added. And, he said, the ripple effects of the guide could go beyond the employer community: "Is this a model that we need to support for cancer care in this country?"

Darling suggested that the guide's impact could go beyond U.S. shores. "What we're finding is that more and more of what we focus on in the U.S. is applicable globally," she said. Indeed, a good percentage of the guide might be applicable around the world despite differences in health care systems, she noted. ☐

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Your iPad—  
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The screenshot shows the Oncology Times iPad app interface. At the top, it displays the date "November 25, 2013" and "Vol. 35 • No. 22". The main header reads "ONCOLOGY TIMES" with a "35th Anniversary" badge. Below the header, there are several featured articles and sections:

- Myeloma: What the Expected Redefinitions Mean for Patient Care** by Heather Lindsey. A sub-headline reads: "There has been a gray zone between the classic categories of active multiple myeloma and smoldering disease. With expected reclassifications coming from the International Myeloma Working Group, some patients with smoldering multiple myeloma now managed by observation only for disease progression may now be eligible for treatment. Among the many resulting clinical implications are questions about the tradeoffs between side effects and potential benefits."
- Drug Shortages** section featuring "ramucirumab".
- PATIENT'S Hope Guide: Final** section with sub-points: "Key Takes on Health Care Reform and Smarter Research", "NSCLC: Patient QOL Reports Predict Outcomes after Radiation", and "Avoiding Hippocampus During RT Aids Memory Preservation".
- ASH President on FDA's Newest Actions**.
- Priority Review for Ramucirumab for Gastric Cancer: Concerns, Though, from a Lead Recruiter to the Trial**.

At the bottom, there is a section titled "[ ALSO ] SHOP TALK" with a list of articles including "Lymphoma in Pregnancy: Few Complications with Chemotherapy", "MIRKAEI SHARES: What Next Clinical Cancer Research", "Whole-Brain RT Not Needed in CNS Lymphoma Patients", "A Critical Look at E-Cigarettes", "Oophorectomy: Chemotherapy for BRCA1-Positive Breast Cancer", "Best Cancer RT as Chest Lymph Node Excision Survival", "Gene Linked to Childhood Leukemia", and "Improving Sun-Protection Practices in Children".