

# THE **CANCER** LETTER

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Vol. 38 No. 8  
Feb. 24, 2012

© Copyright 2012 The Cancer Letter Inc.  
All rights reserved. Price \$405 Per Year.  
To subscribe, call 800-513-7042  
or visit [www.cancerletter.com](http://www.cancerletter.com).

## Drug Shortages

### **FDA Relies On Importation, Fast Approval And Early Reporting to Combat Shortages**

*By Conor Hale and Paul Goldberg*

FDA announced a series of measures to combat shortages of generic drugs in oncology.

At a briefing Feb. 21, the agency said it has:

- Allowed the temporary importation of an Indian-made drug to relieve shortages of Doxil (doxorubicin hydrochloride liposome injection). Despite being on the market, the imported drug, Lipodox, will remain unapproved in the U.S.

- Averted a shortage of methotrexate after the drug's manufacturer, Ben Venue Laboratories, suspended operations at its production facility. FDA expedited the review of an alternative manufacturer's application for preservative-free methotrexate.

- Published a draft guidance requesting an increase in voluntary notifications of shortages by the industry. Sole producers of drugs deemed "life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition" are already required to notify the agency about impending shortages. The draft guidance applies to situations where multiple makers exist.

(Continued to page 2)

## Guest Editorial

### **FDA Must Address Economic Incentives To Resolve Drug Shortages Permanently**

*By Rena Conti*

The FDA's actions earlier this week are an important first step in ensuring the supply of medically necessary drugs.

To attain the long term policy goals of adding domestic manufacturing capacity to produce medically necessary drugs at competitive prices—accessible by all purchasers in the U.S. market—will require the pursuit of complementary policies mindful of intended and unintended consequences.

(Continued to page 6)

## The Duke Scandal

### **South Carolina Clinic, Potti Part Ways**

*By Paul Goldberg*

Anil Potti doesn't work at the Coastal Cancer Center anymore.

The Myrtle Beach practice, which employed the disgraced cancer researcher who had claimed to be a Rhodes Scholar, said his last day at work was Feb. 21, just short of one year from when he began in March 2011.

(Continued to page 7)

## Drug Shortages:

Doxil and Methotrexate

... Page 2

Permanent Solutions

... Page 4

Congressional Letter  
To Ben Venue  
Laboratories

... Page 4

## In Brief:

Potti Press Release  
From Coastal Cancer  
Center

... Page 8

# 195 Drug Shortages Averted Through Early Reporting

(Continued from page 1)

- Expressed support for bipartisan legislation that would provide user fee funding for the agency to manage the drug shortages. Such a bill would require companies to report all prescription drug shortages and give FDA the authority to enforce these requirements.

The agency said that the number of early notifications has increased since President Barack Obama issued an executive order Oct. 31, 2011, directing FDA to use all available administrative tools to combat drug shortages.

On the day the executive order was issued, FDA sent a letter to drug manufacturers suggesting they report events beyond the mandatory requirements, such as: delays in acquiring raw materials, production problems, adjustments or interruptions, import delays, and unexpected increases in demand.

The executive order and FDA's letter to manufacturers have resulted in a six-fold increase in voluntary notifications by industry, the agency said. In 2011, there were a total of 195 drug shortages prevented. Since the executive order, FDA has prevented 114 drug shortages.

According to the draft guidance, an "analysis of 127 drug shortages between Jan. 1, 2010 and Aug. 26, 2011 showed that approximately 60 percent of the shortages were caused by circumstances that may have been avoided or mitigated if the manufacturer

had undertaken enhanced redundancy or contingency planning." The guidance encouraged manufacturers to contact the agency if they plan on developing new contingency plans to discuss additional manufacturing sites, production lines and suppliers.

"Through the collaborative work of FDA, industry, and other stakeholders, patients and families waiting for these products or anxious about their availability should now be able to get the medication they need," said FDA Commissioner Margaret Hamburg.

"We've increased staff in the FDA drug shortage program. We now have 11 full-time staff working on this problem. A broader group of individuals step in as needed—doctors, scientists, inspectors, and members of our offices of generic drugs and compliance.

"Our actions include the continued development of a tracking database for drug shortages, and sharing the information with the Justice Department to address issues of stockpiling, so-called gray markets, and exorbitant pricing of drugs that are in short supply," said Hamburg.

## Doxil and Methotrexate

"Over the past 24 months, it's become very clear that what causes the drug shortage program is multifactorial," said Len Lichtenfeld, deputy chief medical officer of the American Cancer Society. "What causes the shortage for one drug may not be the cause for another drug.

"However that doesn't make life any easier for the parents of children with cancer who may not be able to get methotrexate. Or for doctors who cannot treat the children or adults with other forms of leukemia, because they can't drugs such as cytarabine. Or, for that matter, for ovarian cancer patients who are not able to get Doxil."

"The current drug shortage has become a daily nightmare for patients, their families, and those who treat them," he said. "And as we have researched and worked to try and identify solutions to this issue, it has become very clear that there is unfortunately not one simple solution." At the briefing earlier this week, the agency focused on the management of shortages of two cancer drugs: Doxil and methotrexate.

Doxil is used in multiple treatment regimens, including treatment of ovarian cancer after failure of platinum-based chemotherapy. The drug is also indicated for use in AIDS-related Kaposi's sarcoma and multiple myeloma.

"Lipodox, supplied by Sun Pharma Global FZE and its authorized distributor, Caraco Pharmaceutical



® The Cancer Letter is a registered trademark.

**Editor & Publisher:** Paul Goldberg

**Copy Editor:** Conor Hale

Editorial, Subscriptions and Customer Service:

202-362-1809 Fax: 202-379-1787

PO Box 9905, Washington DC 20016

General Information: [www.cancerletter.com](http://www.cancerletter.com)

Subscription \$405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd.

Laboratories, will be available starting today,” said Hamburg Feb. 21.

Lipodox will serve as a substitute for Doxil. FDA’s exercise of enforcement discretion is a temporary, limited arrangement specific to these companies. Lipodox is manufactured in India.

“Lipodox remains unapproved by FDA for the U.S. market—but when a critical drug is unavailable, and a substitute can produce a comparable outcome, *and* it has been evaluated by us for quality and for safety—we use our enforcement discretion to allow for its temporary and limited use,” said Hamburg.

The agency said that temporary importation of unapproved foreign drugs is considered in rare cases when there is a shortage of an approved drug that is critical to patients and the shortage cannot be resolved in a timely fashion with FDA-approved drugs.

When a company is identified that is willing and able to import the needed drug product, FDA evaluates the foreign-approved drug to ensure that it is of adequate quality and that the drug does not pose significant risks for U.S. patients.

To combat the shortage of methotrexate, a drug used to treat many forms of cancer and other serious diseases, FDA engaged many firms to assist in maintaining supplies.

One formulation of the drug—preservative-free methotrexate—is used in the intrathecal treatment of children with acute lymphocytic leukemia and for high-dose therapy of osteosarcoma.

The Feb. 21 panel included Sara Stuckey—whose six-year-old son, Nate, was diagnosed with ALL in 2009, and has since been undergoing treatment with methotrexate. Nate goes through treatment once every three months.

Recently, the Stuckey family was told that their clinic only had enough methotrexate for Nate’s next treatment—and that after that they might have to seek other options, due to shortages of the drug.

“I can assure you that the conversation of telling parents about their child’s cancer diagnosis is very difficult, but the distress of this conversation was always alleviated somewhat because, in most cases, I was able to tell them about the very effective therapy that we had available, and the realistic chance that their child would be cured,” said panel member Michael Link, president of the American Society of Clinical Oncology. “This conversation has recently changed.”

“Telling parents that, with years of research, we have developed the recipe to treat their child’s cancer—but that the essential ingredients are unavailable today—

is unimaginably painful,” said Link.

The shortage became inevitable when methotrexate’s sponsor, Ben Venue, said it would shut down production of the drug. The circumstances leading up to that decision are the subject of a congressional investigation.

FDA said it worked with Ben Venue to release already manufactured preservative-free methotrexate.

Also, FDA prioritized review and then approved a preservative-free methotrexate manufactured by APP Pharmaceuticals. APP’s application for preservative-free methotrexate was a supplement to its previously approved generic drug application, which the firm had previously discontinued.

“When we were first informed of the shortage of methotrexate injection, we took a two-pronged approach,” said panel member Mitchell Ehrlich, vice president of quality assurance at APP.

“First, we began the process of significantly increasing production of the preservative-containing methotrexate injection, taking our output over the course of the next few weeks to nearly four times our historical rate.

“Second, we worked collaboratively with the [FDA Center for Drug Evaluation and Research]’s drug shortage program to expedite approval of our pending application for preservative-free methotrexate injection,” said Ehrlich.

“As soon as we received notification of the approval, we immediately began the process of scheduling production, so that in the next four to six weeks we will be able to supply clinicians with this critically needed drug.”

Hamburg said the APP product would become available in March.

“[APP] responded promptly to our outreach on the need for more preservative-free methotrexate, and expedited standing up new manufacturing capacity,” said Hamburg. “FDA prioritized their application, as we do for any drug in short supply.”

---

## INSTITUTIONAL PLANS

allow everyone in your organization to read  
**The Cancer Letter and The Clinical Cancer Letter.**

Find subscription plans by clicking Join Now at:

<http://www.cancerletter.com/>

---

Another company, Hospira Inc., also expedited the release of additional supplies of the drug, resulting in 31,000 vials of new product—enough for one month's worth of demand—and began shipping to hundreds of U.S. hospitals and treatment centers.

FDA is also working with other manufacturers—Mylan and Sandoz Pharmaceuticals—in order to meet demand, the agency said.

"Our ability to increase methotrexate production is contingent upon two things: additional active ingredient and streamlined systems for production," said Michael Ball, CEO of Hospira. "Working in close cooperation with the FDA, we were able to achieve both."

"As we speak, we are transporting over 100 kilos of active ingredient from locations from around the world to our manufacturing facility. As a result, next week we will release an additional 34,000 vials, another month's worth of inventory, to meet the full market demand.

"In mid-March, we will release another 55,000 units—which will meet the market's full demand, but also keep a safety stock on hand," he said.

"The agency's rapid response has been unbelievable in this entire situation, and they have been tireless in their efforts to help us avert further shortage situations."

### **Permanent Solutions**

Many panel members made direct calls to Congress to pass legislation addressing the drug shortage problem.

"Let me give a few names: cisplatin, doxorubicin, daunorubicin, etoposide, leucovorin, thiotepa, vinblastine," said Peter Adamson, chair of the Children's Oncology Group. "These are all anti-cancer drugs discovered 30, 40 years ago. Each of those drugs is an essential part of curing childhood cancer. They all continue to be on the FDA drug shortage list. There are potential future crises waiting to happen."

"ASCO believes there are three critical elements that must be part of the long-term solution," said Link. "First, FDA needs to have information on manufacturing delays or market withdrawals as far in advance as possible.

"Second, we have to address the role that economics plays in causing shortages. For a variety of reasons, the market is unable to respond in expected ways when there is high demand and limited supply of generic medications. Addressing this aspect of drug shortages, including pricing and incentives to ensure manufacturers incorporate redundancies and contingency planning in their production, is a necessary and critical aspect of any solution.

"And third, the generic user fee plan must be passed to provide resources for reviewing applications in a timely way. This will also enable FDA to complete inspections and work with companies to address issues that might otherwise lead to shortages."

"The data is clear that early notification has a significant and meaningful impact on drug shortages," said Hamburg. "We fully support bipartisan legislation to require finished product manufacturers to report all prescription drug shortages to the FDA, and to give FDA new authority to enforce these requirements."

Legislation should be introduced rapidly, COG's Adamson said.

"I certainly understand that passing legislation is complex. It is difficult," said Adamson. "I suspect, however, that it is no more difficult than curing a child with cancer. And I can absolutely tell you that it is no more complex or difficult than what children every day face in their fight against childhood cancer.

"We can induce a remission in a child with ALL within four weeks' time. That's the first step towards cure. It's complex treatment. It's difficult treatment. But if we can induce a remission in children with leukemia within four weeks, I would challenge our colleagues in Washington to enact legislation in four weeks' time."

### **Congressional Letter to Ben Venue**

In a related development, a group of Senators wrote a letter to Ben Venue Laboratories Feb. 16, seeking information about the company's role in the methotrexate shortage.

"We are deeply troubled by recent reports of the acute and prevalent shortages of Methotrexate as well as other lifesaving drugs for patients across the country," wrote Sens. Richard Blumenthal (D-Conn.), Tom Harkin (D-Iowa), Mike Enzi (R-Wyo.), Lamar Alexander (R-Tenn.), and Bob Casey (D-Pa.).

"While Ben Venue has publicly stated that supplies of methotrexate will become available in stages and that certain portions of its plant will return to production in the first quarter of 2012, no timeline has been given to patients and providers with specific information as to when production of methotrexate will fully resume, and how much product will be available in the meantime."

The senators requested responses to a number of questions, including which "significant manufacturing and quality concerns" led the company to suspend production; the relationship among Boehringer Ingelheim, Bedford Laboratories and Ben Venue Laboratories as it relates to production and distribution of Methotrexate, as well as the factors that led Bedford



to suspend the distribution of all Ben Venue products; the date on which the company first reported the need to suspend production of methotrexate to FDA and what actions the company has subsequently taken to work with FDA to mitigate the adverse consequences of this suspension; and the company's timeline for restoring full manufacturing capacity for methotrexate.

Harkin is the chairman of the Senate Health, Education, Labor, and Pensions Committee; Enzi is the ranking member; and Blumenthal, Alexander, and Casey are committee members.

*The text of the letter follows:*

George Doyle III, President and Chief Operating Officer  
Ben Venue Laboratories  
c/o Bedford Laboratories  
300 Northfield Road  
Bedford, OH 44146

Dear Mr. Doyle,

We are deeply troubled by recent reports of the acute and prevalent shortages of Methotrexate as well as other lifesaving drugs for patients across the country.

As you know, Methotrexate is a generic product that is used by millions of Americans to treat pediatric leukemia as well as severe autoimmune conditions. Recent reports, including an article this weekend in The New York Times, have indicated that Ben Venue Laboratories—one of the nation's largest suppliers of injectable preservative-free Methotrexate—voluntarily suspended operations at its Bedford, Ohio, plant in November because of "significant manufacturing and quality concerns."

Of even greater concern, these same reports also indicated that the publicly available supply of these drugs may be exhausted within the next few weeks. While Ben Venue has publicly stated that supplies of Methotrexate will become available in stages and that certain portions of its plant will return to production in the first quarter of 2012, no timeline has been given to patients and providers with specific information as to when production of Methotrexate will fully resume, and how much product will be available in the meantime.

Given the nature of this shortage, the serious health impacts it is having at the state and national levels, as well as Congress' ongoing efforts to address such drug shortages, we would request that you please provide the following information by Feb. 24, 2012:

1. The specific "significant manufacturing and quality concerns" that led your company to suspend production, including what preventative maintenance

and re-qualifications of equipment were overdue as noted in your Dec. 23, 2011 press release;

2. Copies of any inspection findings regarding your facility by FDA, EMEA and/or any other global agencies as referenced in your Dec. 23, 2011 press release;

3. The date on which Company management learned of these concerns and how they were brought to your attention;

4. The relationship among Boehringer Ingelheim, Bedford Laboratories and Ben Venue Laboratories as it relates to production and distribution of Methotrexate, and the factors that led Bedford to suspend the distribution of all Ben Venue products;

5. The date on which your company first reported the need to suspend production of Methotrexate to the Food and Drug Administration and what actions your company has subsequently taken to work with the Food and Drug Administration to mitigate the adverse consequences of this suspension;

6. A description of what other actions your company has taken to address the identified "significant manufacturing and quality concerns;"

7. Your company's timeline for restoring full manufacturing capacity for Methotrexate, including whether it can be manufactured other than in the North facility (described in your December 2011 press release as being unavailable until fourth quarter 2012), and how your company intends to allocate available stock until prior capacity is restored; and

8. Whether you believe that reimbursements for Methotrexate played a factor in the current overall shortage. As part of your answer please provide the quarterly reported Average Sales Prices (ASP), total annual revenues, total annual sales, and production costs for the previous two years associated with your sales of Methotrexate.

---

**Advertise your meetings and recruitments**  
In The Cancer Letter and The Clinical Cancer Letter  
Find more information at: [www.cancerletter.com](http://www.cancerletter.com)

---

---

**Follow us on Twitter: @TheCancerLetter**

---

*Guest Editorial*

## **Econ 101: Drugs in Short Supply Should Command Higher Prices**

(Continued from page 1)

The agency announced a threefold approach to increase the supply of cancer drugs in shortage:

First, Lipodox will be imported to replace supply of the cancer drug Doxil. FDA's ability to arrange limited, temporary importation of Lipodox supplies is firmly within their regulatory purview.

Second, the FDA has approved a new manufacturer of preservative-free formulation of methotrexate, APP Pharmaceuticals Inc.

Third, in response to President Obama's Oct. 31, 2011 executive order on prescription drug shortages, the FDA issued draft guidance to industry on detailed requirements for both mandatory and voluntary notifications to the FDA of issues that could result in a drug shortage or supply disruption.

These policies should be lauded as striking a good balance between the short-run benefits of tailoring regulatory responses to meet urgent patient needs against safety concerns, and the potential long-term reductions in competition.

For example, the contract between the FDA and Sun Pharma Global FZE and Caraco Pharmaceutical Laboratories Ltd. to provide Lipodox will increase the supply of treatments for specific, cancer-afflicted, vulnerable patient populations in the short term.

Lipodox is expected to be available for distribution in the U.S. in the next couple of weeks. While importation has been vilified by commentators as placing the U.S. population at risk from the consumption of "low quality drugs," this concern may be mitigated in this example.

Sun Pharma manufactures Lipodox in a manufacturing facility in Halol, India. To approve the sale in the U.S. market, the FDA must, by statute, complete an independent evaluation of the drug and the supplier's manufacturing facilities to ensure that the drug is of adequate quality, and will not pose significant health risks for U.S. patients.

Only after the successful evaluation of these factors may the FDA exercise its "executive discretion" to allow the importation of a foreign drug into the U.S. market.

The FDA's importation policy is limited by duration and in scope to a drug widely considered to be "medically necessary." If the duration of the Lipodox supply were to be extended, then FDA should release details of the periodicity of drug and facility inspections

to the public, to alleviate quality concerns.

The temporary and limited nature of the importation contract between the FDA and Sun Pharma suggests the supply of Doxil may become short again if no domestic manufacturers are able or willing to increase production in the near term. Clarity on other actions the FDA might be pursuing to increase the willingness and ability of domestic manufacturers to supply Doxil is needed.

The FDA's policy on preservative-free methotrexate will also increase supply of this "medically necessary" drug by multiple manufacturers. APP expects their new supply of preservative-free methotrexate to become available in March.

In the meantime, the FDA has been working with Ben Venue to release already manufactured preservative-free methotrexate, following the FDA's confirmation of its safety. This supply is currently available.

In addition, Hospira has announced the expedited release of additional supplies, resulting in 31,000 vials of new product, being shipped to U.S. hospitals and treatment centers this week. FDA reports they are actively working with other manufacturers of methotrexate to increase production in order to meet patient demand.

Finally, the additional policies adopted by the FDA to encourage the voluntary and mandatory notification of product supply interruptions and molecule-specific deactivations may have a significant and positive impact on the incidence rate and the duration of drug shortages over time.

The historical U.S. manufacturers of Doxil and methotrexate, like the manufacturers of other cancer drugs, generate revenue from reducing costs and making drugs that have the highest revenue potential. Therefore, we should expect firms to shift away from manufacturing older drugs with limited demand to higher revenue-producing drugs over time.

These reporting policies act as a "stick" to compel manufacturers to notify public agencies of their plans to reduce production and/or retire lines of drug production. They also may increase regulatory oversight of the quality of contract manufacturers, such as Ben Venue.

These policies complement the "carrot" offered by FDA to domestic firms to reduce the short-term costs of producing these drugs through the expedited review of ANDAs and clearance of existing supply lots by the FDA. It is important for the FDA to ensure the privacy of firms in meeting these reporting requirements, lest public policy unintentionally facilitate the firms' collective monitoring of total supply.

Maintaining competition in these and related drug

markets is an important policy goal, since competition aids the adequate supply and quality of medically necessary drugs at non-monopoly (read, “low”) prices.

Yet, one aspect of these policies that was not adequately addressed by the FDA’s announcement is the system for distributing increases in the supply of Lipodox and preservative-free methotrexate to U.S. hospitals and provider groups.

Not all parts of the country or all providers are equally affected by these specific drug shortages, even though reports of them are widespread. It is likely that small, community, low-volume oncology practices may be the most vulnerable to interruptions in these products’ supply—and the most in need of increased access to these drugs.

Furthermore, pricing guidelines for the manufacturer of imported Lipodox and APP’s preservative-free methotrexate are not provided by the FDA’s announcement.

Economics 101 suggests manufacturers of medically necessary drugs in scarce supply should be able to command a high price from purchasers. It remains to be seen whether Sun Pharma and APP will set the prices of these products above historically observed market prices for these drugs.

Clarity is also needed regarding whether manufacturers will be able to set the prices of these drugs based on purchasers’ volume, or other indicators of willingness to pay (so-called “price discrimination”).

If price-discrimination is practiced by these firms, purchasers facing low prices for Doxil in particular may attempt to hoard supply in anticipation that prices may go up again if supplies dwindle.

Again, it is likely that low-volume, community oncology practices remain vulnerable to hoarding and/or price gouging if the market is left to clear on its own.

Finally, the FDA also endorsed legislation that would provide user fee funding for the FDA to manage the drug shortages. User fees should be understood as a “tax” placed on the industry. It is likely these fees will be passed on to consumers in the form of higher prices.

While user fees may act as an additional incentive for manufacturers to incorporate redundancies and contingency planning into their production planning, there is no requirement that they do so in the policy outlined by the FDA.

*Rena Conti is a health economist in the University of Chicago Section of Hematology/Oncology and Department of Pediatrics, and is a faculty affiliate at the University of Chicago Comprehensive Cancer Center.*

## **Selected References for Further Reading**

- Chabner BA. Drug Shortages - A Critical Challenge for the Generic-Drug Market. *N Engl J Med*. 2011; Epub Oct. 31 [ahead of print]. PubMed PMID: 22040167.
- IMS Institute for Healthcare Informatics. Drug Shortages: A closer look at products, suppliers and volume volatility. November 2011.
- MEDPAC / Miller, ME. Testimony: Medicare Part B Drugs and Oncology. Statement Before the U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Health. July 13, 2006.
- Office of the Assistant Secretary for Planning (ASPE) and Evaluation and Office of Science and Data Policy, U.S. Department of Health and Human Services (Haninger K, Jessup A, Koehler K). ASPE Issue Brief: Economic Analysis of the Causes of Drug Shortages. October 2011.
- U.S. Department of Health and Human Services and U.S. Food and Drug Administration. A Review of FDA’s Approach to Medical Product Shortages. Oct. 31, 2011.

## **The Duke Scandal**

### **S.C. Practice: Potti was Hired Based on Duke Recommendations**

(Continued from page 1)

The practice has been under siege by local media after the 60 Minutes report that aired Feb. 12. The segment reported that after causing a debacle at Duke, where he is accused of having falsified both data and credentials, Potti obtained a South Carolina license and landed in Myrtle Beach.

The segment showed Potti’s name on the sign of the practice’s satellite office in the town of Loris.

Initially, the practice’s founder claimed to be unaware of the details that were presented in the 60 Minutes report “Deception at Duke.”

“We had no idea 60 Minutes was going to do this,” said Coastal Cancer Center’s Lawrence Holt to a publication called SCNow. “It caught us out of the blue.”

Many of the same details that made it into the 60 Minutes piece had previously appeared in *The Cancer Letter*, as well as in a variety of high-profile news organizations worldwide, including *The Economist* and on the front page of *The New York Times*.

---

**Follow us on Twitter: @TheCancerLetter**

---

Now, after relentless publicity, the practice and the physician have ended their association. In a carefully worded press release, the Coastal Cancer Center avoided using the words “resigned” or “fired,” and instead pointed to Potti’s former Duke colleagues, who had given him glowing letters of recommendation. The letters were a “key factor” in Potti’s hiring.

Potti’s former Duke colleagues did indeed write glowing letters of recommendations to the South Carolina licensure board. One such letter was penned by Jeffrey Crawford, the George Barth Geller Professor for Research in Cancer and chief of medical oncology at Duke. Crawford addressed his letter to Holt, but the recommendation ended up in Potti’s application file at the licensure board.

“His clinical skills are excellent,” Crawford wrote in the letter dated Jan. 7, 2011. “During his tenure at Duke, Anil developed an impressive research program and helped the careers of a number of our fellows and junior faculty. He was always willing to help others around him and was an ideal model ‘team player.’ Despite a very active research program, Anil maintained his dedication to patient care and this always came first for him.”

Afterward, Crawford said he regrets writing the letter. “In retrospect, I realize that it was a mistake to send this letter without understanding the situation as I do today,” Crawford said in an email to The Cancer Letter (The Cancer Letter, Dec. 9, 2011).

Though Duke continues to claim that no patient was harmed in three clinical trials that tested Potti’s scientific findings, the institution did settle 11 malpractice claims filed by former patients, and is in the midst of fighting two lawsuits stemming from Potti’s work.

Meanwhile, the world’s premier medical journals have retracted Potti’s papers.

Papers based on Potti’s data have been retracted in The New England Journal of Medicine, Nature Medicine, The Lancet Oncology, PLoS ONE and Blood. The Journal of Clinical Oncology has retracted two papers. The most recent retraction was published by Clinical Cancer Research earlier this week: <http://bit.ly/yO2TKS>

*The text of the press release by Potti’s former employer follows:*

Dr. Anil Potti, MD is no longer associated with Coastal Cancer Center of Myrtle Beach, S.C. Dr. Potti, who saw patients primarily at Coastal Cancer Center’s Loris, S.C. and Brunswick County, N.C. facilities,

served his final day on Feb. 21st. Potti originally joined Coastal Cancer Center as an oncologist in March 2011.

“A recent 60 Minutes story concerning an investigation of Duke University’s cancer research programs and Dr. Potti’s work there prompted many concerned people to contact Coastal Cancer Center with comments and questions,” said Lawrence B. Holt, Jr., MD, FACP, President of Coastal Cancer Center. “It has become obvious that this issue is going to take precious focus away from patient care. Coastal Cancer Center is staffed by incredibly caring people who want and need to concentrate on providing outstanding patient care.”

Coastal Cancer Center conducted a deep and thorough investigation of Potti’s credentials before hiring him. Potti received numerous letters of strong recommendation from key members of the medical community at Duke University where Potti had worked before coming to the Grand Strand.

“We received glowing references about Dr. Potti’s character and skills from the highest ranks of the Duke University School of Medicine and Duke University Medical Center,” said Holt. “We were assured by Duke Medical’s leaders that Anil was ‘outstanding in all categories,’ ‘had excellent clinical skills’ and that he had conducted himself at Duke with ‘honesty, integrity and humility.’ One Duke University director even went so far as to say he would be pleased to have Dr. Potti as the treating physician ‘if my own family had unfortunately contracted a cancer.’ Letters of recommendation came in from the chief of Duke Medical’s Division of Medical Oncology, the Chair of the Department of Medicine, the Director of Hematologic Malignancies Program, and several professors.

“During the time that Dr. Potti has been with us,” continued Holt, “he has been an exemplary physician whose caring ways have made him extremely popular with patients. We will miss him.”

During his time on staff at Coastal Cancer Center, Dr. Potti became an active part of the Grand Strand medical community, many of whom have reached out to him in the days since the 60 Minutes story aired.

“We have been touched and heartened by the outpouring of support for Anil that has come from the local medical community,” says Holt. “Like those of us at the Cancer Center, other physicians recognize him as an exceptional doctor and colleague.”

Dr. Holt and other Coastal Cancer Center physicians will personally assume the care of Dr. Potti’s patients.