



## Updates to Recommendations for Safe Chemotherapy Handling

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Although several oral antineoplastic agents were in existence and utilized prior to 2000, chemotherapy administration had traditionally occurred via intravenous infusion in a hospital, clinic, or office setting. In 1990 the American Society of Health-System Pharmacists (ASHP) published revisions to its technical assistance bulletin (TAB) on cytotoxic and hazardous drug handling. It was updated in 2004 to include guidelines and recommendations from the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH), published in 1995 and 2004, respectively. The 2004 TAB<sup>1</sup> provided guidance for the safe handling of injectable cytotoxic and hazardous drugs, however the topic of oral agents was largely overlooked.

In May 2001 imatinib (Gleevec<sup>®</sup>) was approved for the treatment of chronic myelogenous leukemia, and the landscape of chemotherapy administration was forever changed. The advantages to oral chemotherapy, as described in the literature, have been numerous: control over the environment in which treatment is received, increased convenience and reduction in travel costs, avoidance of intravenous

access issues, potential increases in quality of life, and decreased utilization of healthcare resources.<sup>2-4</sup> Despite the many advantages, however, oral chemotherapy also has been identified as a serious patient safety concern. Some of the known concerns with oral chemotherapy include over- and underdosing, limited and difficult monitoring of adverse events, patient nonadherence, and accidental exposure for patients and caregivers.

As oral chemotherapeutic agents have become more integrated into treatment plans, more comprehensive recommendations have emerged to better guide the safe handling of these agents across the spectrum of stakeholders, including manufacturers and distributors, healthcare professionals, and patients. An international expert panel of pharmacists, including HOPA members Susan Goodin, PharmD; Niesha Griffith, RPH MS FASHP; Beth Chen, PharmD; and Rowena Schwartz, PharmD, examined 14 guidelines and policies and 8 relevant publications from North America and Europe. The result was the development of a set of recommendations for the safe handling of oral chemotherapy agents.<sup>5</sup>

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**Table 1** presents the main points from the ASHP 2004 TAB and an article published by Goodin and colleagues (2011)<sup>5</sup>. Please refer to individual guidelines for complete recommendations because this table is not all inclusive.

Take a look at your practice. How safely is oral chemotherapy being handled?

## References

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**Table 1. Comparison of ASHP's TAB (2004) and Goodin and Colleagues' Findings (2011)**

ASHP (2004) <sup>4</sup>	Goodin et al. (2011) <sup>5</sup>
<p><b>Manufacturers, distributors</b></p>	<ul style="list-style-type: none"> <li>▪ Safety programs must identify and include all workers who may be at risk of exposure because packaging may be contaminated.</li> <li>▪ Oral chemotherapeutic agents must include proper labeling by the manufacturer or distributor with a distinctive identifier that notifies personnel receiving them to wear appropriate personal protective equipment (PPE) during their handling.</li> <li>▪ Sealing drugs in plastic bags at the distributor level provides an additional level of safety.</li> </ul>
<p><b>Healthcare professionals</b></p>	<p><b>Packaging and segregation</b></p> <ul style="list-style-type: none"> <li>▪ Avoid contamination prior to distribution</li> <li>▪ Packaging material: Durability, able to contain any accidental leakage during handling and transport, and tamper proof</li> <li>▪ The package label should indicate cytotoxicity.</li> <li>▪ Package labeling should be intact.</li> <li>▪ Separate storage and transportation of oral cytotoxic and noncytotoxic agents</li> </ul> <p><b>Minimization of handling oral chemotherapeutic agents</b></p> <ul style="list-style-type: none"> <li>▪ Package size should reflect the appropriate number of tablets or capsules based on the number needed for one cycle of therapy.</li> <li>▪ A liquid formulation or information for suspension compounding should be available.</li> </ul> <p><b>Educational materials</b></p> <ul style="list-style-type: none"> <li>▪ Educational materials for safe handling for each stakeholder</li> <li>▪ Update patient education materials as new information is available.</li> </ul> <p><b>Storage</b></p> <ul style="list-style-type: none"> <li>▪ Proper storage and handling by healthcare professionals to prevent accidental exposure and ensure integrity</li> <li>▪ Designated storage per manufacturer's instructions and specifications</li> </ul>
<ul style="list-style-type: none"> <li>▪ Safety programs must identify and include all workers who may be at risk of exposure because packaging may be contaminated.</li> <li>▪ Oral chemotherapeutic agents must include proper labeling by the manufacturer or distributor with a distinctive identifier that notifies personnel receiving them to wear appropriate personal protective equipment (PPE) during their handling.</li> <li>▪ Sealing drugs in plastic bags at the distributor level provides an additional level of safety.</li> </ul>	<p><b>Safety program</b></p> <ul style="list-style-type: none"> <li>▪ Policies and procedures in place for safe handling</li> <li>▪ Development of a safety program, addressing all aspects of safe handling</li> <li>▪ Required to have a material safety data sheet available for all hazardous agents</li> <li>▪ Clear labeling of hazardous medications</li> <li>▪ Visual examination of products for damage or breakage</li> <li>▪ Policies and procedures in place for handling damaged cartons or containers of hazardous drugs</li> <li>▪ Fit testing available for respirators</li> </ul>

Table 1. Comparison of ASHP's TAB (2004) and Goodin and Colleagues' Findings (2011) (continued)

ASHP (2004) <sup>4</sup>	Goodin et al. (2011) <sup>5</sup>
<p><b>Healthcare professionals</b> (Continued)</p>	<p><b>Labeling and packaging from point of receipt</b></p> <ul style="list-style-type: none"> <li>▪ Storage areas must be distinctively labeled and segregated.</li> <li>▪ Storage bins: High fronts on shelves to prevent falling, appropriately sized, separated to reduce errors</li> <li>▪ Staff should wear double gloves when stocking and inventorying.</li> <li>▪ Carts or other transport devices must be designed with guards to protect against falling and breakage.</li> <li>▪ Safety training for all transporting hazardous drugs with spill kits immediately accessible</li> <li>▪ Warning labels and signs must be clear to non-English readers.</li> </ul> <p><b>Environment</b></p> <ul style="list-style-type: none"> <li>▪ Compounding should occur in a controlled area with limited access.</li> <li>▪ Negative pressure environment or area surrounded by an airlock or anteroom preferred</li> <li>▪ Only individuals trained in the administration of hazardous drugs should do so.</li> <li>▪ Eating, drinking, applying makeup, and storing foodstuffs should be avoided in patient care areas while hazardous drugs are administered.</li> <li>▪ Inpatient therapy: Hazardous drugs should be scheduled to reduce exposure of family members and ancillary staff and to avoid the potential contamination of dietary trays and personnel.</li> <li>▪ Outpatient areas: Design must include surfaces that are readily cleaned and decontaminated. Avoid upholstered and carpeted surfaces.</li> </ul> <p><b>Ventilation controls</b></p> <ul style="list-style-type: none"> <li>▪ Designed to eliminate or reduce worker exposure</li> <li>▪ For compounding of sterile hazardous drugs, class II or III BSC or an isolator intended for aseptic preparation and containment is required.</li> </ul> <p><b>PPE</b></p> <ul style="list-style-type: none"> <li>▪ Gloves must be worn at all times when handling drug packaging, cartons, and vials, including while performing inventory control procedures and when gathering hazardous drugs and supplies for compounding a batch or single dose.</li> <li>▪ Hands should be thoroughly washed before donning gloves and after removing them.</li> <li>▪ Gowns or coveralls are worn during the compounding of sterile preparations to protect the preparation from the worker, to protect the worker from the preparation, or both.</li> <li>▪ Additional PPE: Eye and face protection should be used whenever there is a possibility of exposure from splashing or uncontrolled aerosolization of hazardous drugs.</li> </ul>
	<p><b>Handling</b></p> <ul style="list-style-type: none"> <li>▪ Correct use of PPE</li> <li>▪ Do not dispense using automatic counting machines.</li> <li>▪ Use disposable gloves for dispensing, with hand washing before and after glove applications.</li> <li>▪ Dosage form manipulations (compounding, crushing, cutting, or splitting) performed in a BSC with PPE</li> <li>▪ Pharmacist (or other qualified professional) should attempt to limit additional handling of hazardous medications by other healthcare professionals.</li> <li>▪ If storing and dispensing: Written emergency plan in the event of a spill or accidental exposure; recommend annual spill simulation exercises</li> <li>▪ Have available a readily accessible, updated list of hazardous medications</li> </ul> <p><b>Disposal and cleaning of contaminated materials</b></p> <ul style="list-style-type: none"> <li>▪ All disposable protective clothing and materials should be disposed of as cytotoxic waste.</li> <li>▪ All exposed nondisposable materials should be thoroughly washed or decontaminated after use.</li> </ul> <p><b>Training and competencies for safe handling</b></p> <ul style="list-style-type: none"> <li>▪ Healthcare workers should attend orientation programs and routine training courses and complete competencies associated with these training programs.</li> <li>▪ Establish a primary educator.</li> <li>▪ Training and competency for accidental exposures and proper disposal</li> <li>▪ All staff who may come in contact with oral chemotherapy agents should undergo this training.</li> </ul>

Table 1. Comparison of ASHP's TAB (2004) and Goodin and Colleagues' Findings (2011) (continued)

ASHP (2004) <sup>4</sup>	Goodin et al. (2011) <sup>5</sup>
<p><b>Healthcare professionals</b> (Continued)</p>	<p><b>Preparation and handling of noninjectable hazardous drug dosage forms</b></p> <ul style="list-style-type: none"> <li>▪ Procedures for the preparation and the use of equipment (e.g., class I BSCs or bench-top hoods with HEPA filters) must be developed to avoid the release of aerosolized powder or liquid into the environment during manipulation of hazardous drugs.</li> </ul> <p><b>Decontamination, deactivation, and cleaning</b></p> <ul style="list-style-type: none"> <li>▪ Decontamination of BSCs and isolators should be conducted per manufacturer recommendations.</li> <li>▪ Sodium hypochlorite solution is often recommended as an appropriate deactivating agent.</li> </ul> <p><b>Spill management</b></p> <ul style="list-style-type: none"> <li>▪ Policies and procedures must be developed to attempt to prevent spills and to govern cleanup of hazardous drug spills.</li> <li>▪ Written procedures must address who is responsible for spill management and the size and scope of the spill.</li> </ul>
<p><b>Patients and caregivers</b></p>	<p><b>Patients should</b></p> <ul style="list-style-type: none"> <li>▪ review the package label (especially medication name and dosage)</li> <li>▪ ensure that they completely understand when and how to take the medication and ask questions if there is any confusion</li> <li>▪ transport and store medicine as instructed and as outlined on the packaging label</li> <li>▪ use gloves if possible and wash hands thoroughly before and after glove application; if gloves are not worn, tip tablets and capsules from their container/blister pack directly into a disposable medicine cup</li> <li>▪ have caregivers wear gloves at all times while handling both oral chemotherapeutic agents and contaminated items</li> <li>▪ administer the medication as instructed</li> <li>▪ keep a journal of adverse effects; make a list of adverse effects for which the healthcare professional has to be contacted immediately</li> <li>▪ inform other healthcare professionals that you are on oral chemotherapy</li> <li>▪ wash clothes and bed linen separately from other items</li> <li>▪ double flush the toilet after use, during use of, and 4–7 days after discontinuing oral chemotherapy.</li> </ul> <p><b>Patients should not</b></p> <ul style="list-style-type: none"> <li>▪ assume that oral chemotherapy is safer than intravenous chemotherapy</li> <li>▪ leave medication in open areas, near sources of water, in direct sunlight, or where easily accessed by children or pets</li> <li>▪ store medications in the areas where food or drinks are stored or consumed</li> <li>▪ crush, break, or chew tablets</li> <li>▪ double up on or skip doses, unless instructed by a healthcare professional</li> <li>▪ share prescriptions or medication</li> <li>▪ discard medication down the toilet or in the garbage.</li> </ul>

# Proposed Rulemaking Attempts to Clarify 340B Pricing and Orphan Drugs

Carrie Barnhart, PharmD

In 2010 eligibility criteria for participation in the 340B Drug Pricing Program were expanded by the Affordable Care Act. According to new language (with varying interpretations) in the Act, orphan drugs will be excluded from the program.

## Background

Last year several new entities were added to the list of eligible participants for the 340B program. These include certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. The expansion of eligible organizations adds to the previous list of safety-net facilities, which include

- federally qualified health centers
- family planning projects
- facilities providing HIV intervention and treatment (Ryan White Care Act)
- black lung clinics
- hemophilia treatment centers
- native Hawaiian health centers
- urban Indian healthcare facilities
- facilities certified to provide treatment for tuberculosis or sexually transmitted diseases
- disproportionate share hospitals (DSH)
- children's hospitals.

Organizations that meet the requirements of the 340B program of the Public Health Service Act ("covered entities") are able to purchase drugs for outpatient use at defined ceiling prices determined by the Centers for Medicare & Medicaid Services (CMS). The ceiling price is determined by subtracting a rebate amount from the average manufacturer price and is agreed upon by the pharmaceutical manufacturer and the Department of Health and Human Services (HHS).<sup>1</sup> A 2005 Congressional Budget Office report estimated that the ceiling price on drugs purchased through the 340B program was 51% of average wholesale price.<sup>2</sup> Drugs purchased through the 340B program cannot be sold or transferred to another facility.<sup>1</sup>

The Affordable Care Act and the Medicare and Medicaid Extenders Act of 2010 excluded orphan drugs from the 340B program (except at children's hospitals) because of protections allowed in the Orphan Drug Act. The Orphan Drug Act is intended to stimulate research and development of drugs for rare diseases. Congress recognizes that "a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss," and "it is in the public interest to provide such changes and incentives for the development of orphan drugs."<sup>3</sup> Orphan drugs can be developed using federal grant funds, and manufacturers may take advantage of 7-year market exclusivity, tax incentives on clinical trials, and an exemption from standard U.S. Food and Drug Administration (FDA) application fees.<sup>3</sup>

## Intention of Proposed Rulemaking

The exclusion of orphan drugs from the 340B program has caused confusion with manufacturers and covered entities. In response to various interpretations, some manufacturers have stopped selling or stated they will stop selling orphan drug products through the 340B program to avoid unfair pricing implications. Newly eligible healthcare organizations are unsure if they can legally purchase these products through the 340B program or buying groups and whether there are additional requirements for record keeping. Some new participants in the 340B program, such as free-standing cancer hospitals, purchase significant amounts of orphan drugs and would receive little, if any, savings if all orphan drugs are excluded from the 340B program.<sup>1</sup>

One example of a drug that falls under both orphan drug status and 340B is bevacizumab (Avastin®). Bevacizumab has FDA-approved indications for metastatic colorectal cancer, nonsquamous non-small cell lung cancer, metastatic breast cancer, glioblastoma, and metastatic renal cell carcinoma.<sup>4</sup> It is designated as an orphan drug for the following conditions: pancreatic cancer, ovarian cancer, fallopian tube cancer, melanoma, primary peritoneal cancer, hereditary hemorrhagic telangiectasia, and stomach cancer.<sup>5</sup> By excluding orphan drugs from the 340B program, all bevacizumab could be interpreted as excluded from 340B regardless of the disease being treated.

Under the proposed rules, HHS clarifies that the exemption for orphan drugs applies only when they are used for the rare disease for which the orphan drug was designated. This ruling is meant to balance Congress's objective of avoiding the undermining of pricing for orphan drugs and the 340B Drug Pricing Program's intended benefit. Healthcare facilities will be responsible for maintaining auditable records of doses ordered through the 340B program for FDA-approved indications and doses ordered through a separate wholesaler for orphan drug diseases. An alternative is to purchase all drugs with orphan drug designation outside of the 340B program and forgo potential savings.<sup>1</sup> Software programs are available to assist with record keeping and billing for those facilities that order drugs for both inpatient and outpatient use to ensure 340B program purchases are used only for outpatients.<sup>6</sup> However, separating drug purchases by diagnosis may prove to be more of a logistical challenge. HHS does not specify a method of record keeping, nor is it able to estimate the cost of compliance. It is expected that healthcare facilities participating in the 340B program will have a net benefit in 50%–75% of cases in which a drug with both FDA-approved indications and orphan drug status (such as bevacizumab) are used.<sup>1</sup>

## Information Resources

The Health Resources and Services Administration (HRSA) Pharmacy Services Support Center (PSSC) is the government-approved resource for all 340B information. PSSC operates through a contract between HRSA and the American Pharmacists Association. PSSC was created to help federally funded healthcare organizations develop clinically and cost-effective pharmacy services, including optimal use of the 340B Drug Pricing Program. To obtain free information, education, and technical assistance, contact the PSSC at 800.628.6297 or <http://pssc.aphanet.org>.<sup>7</sup>



## References

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# Nominations for HOPA Membership Awards Now Being Accepted



Hematology/Oncology  
Pharmacy Association

[hoparx.org](http://hoparx.org)

The HOPA Nominations & Awards Committee is now accepting nominations for the 2012 Membership Awards Program. Learn more and nominate a qualified candidate today at [www.hoparx.org](http://www.hoparx.org). The deadline for nominations is November 15, 2011.

# HOPA Support for Drug Shortage Bill S. 296: Preserving Access to Life-Saving Medications Act

Ali McBride, PharmD MS, Chair, Legislative Affairs Committee

Tim Tyler, PharmD FCSHP, Vice-Chair, Legislative Affairs Committee

Niesha Griffith, MS RPh FASHP, Board Liaison

The clinical effect of drug shortages has affected numerous patients and practice sites across the country. Drug shortages have not been limited to a particular practice site; shortages have been reported to occur in anesthesiology, infectious disease, electrolyte replacement, and oncology drugs. These shortages continue to impact clinicians, pharmacists, and patients each day. In 2010 211 drugs were listed in the drug shortage database (including an increased number of parenteral drug products), making this year the worst ever for drug shortages. Neither generic nor brand name medications were safe from the shortage. The shortage has led to increased costs, with an estimated financial impact of more than \$200 million annually. The man-hours alone spent planning for the shortage, educating staff, restocking and coding the alternative products, dealing with secondary market vendors, and fielding calls from healthcare practitioners consumes a large portion of pharmacists' time, stealing valuable resources from clinical activities. Throughout the shortages, pharmacists have been committed to ensuring patient safety and providing quality care. However, patient safety has been severely affected by this issue, and several reports suggest that the problem has become a national public health crisis.

HOPA participated in the Drug Shortages Stakeholder Executive Session in Bethesda, MD, on November 5 to address the issue.

The American Society of Health-System Pharmacists along with the American Society of Anesthesiologists, the Institute for Safe Medication Practices, and the American Society of Clinical Oncology and invited participants from the U.S. Food and Drug Administration (FDA), health professional organizations, pharmaceutical manufacturers, and supply chain distributors attended the meeting. The summit report outlines 21 proposed recommendations to improve communication among stakeholders and remove barriers faced by the FDA and drug manufacturers, including

- expanding FDA authority to require manufacturer notification of shortages and market withdrawals
- providing incentives (e.g., tax credits) to manufacturers that produce critical drug products in exchange for a guarantee of continued production
- requiring pharmaceutical manufacturers to confidentially notify the FDA when there is a single active pharmaceutical ingredient or manufacturing source
- establishing an expedited approval pathway for those unapproved drugs that are deemed critical therapies
- enhancing communication among healthcare providers and stakeholders in the pharmaceutical supply chain about the nature and expected duration of shortages
- evaluating and addressing the impact of just-in-time and sole-source inventory practices
- considering distribution options for products in short supply.

The recommendations are being further evaluated and implemented, if appropriate, based on an assessment of feasibility, impact, and resources required for implementation. Compliance with legal requirements (Federal Trade Commission regulations) and avoidance of unintended consequences (hoarding, manufacturing disincentives) will also be factored into this evaluation. The next steps for the Summit's coconveners involve continuing stakeholder collaboration, establishing workgroups to prioritize activities and create action plans, and advocating for change to Congress, the FDA, and other federal agencies.

These recommendations spurred the development of bill S. 296 Preserving Access to Life-Saving Medications Act. The Act, if successful, will provide the FDA with tools to better manage—and hopefully prevent—shortages of life-saving medications. The legislation enables the FDA to work more effectively with the pharmaceutical supply chain to ensure drug availability and enhances the agency's ability to monitor drugs that are vulnerable to shortages in the future. The Preserving Access to Life-Saving Medications Act amends the Federal Food, Drug, and Cosmetic Act that requires a prescription drug manufacturer to notify the Secretary of Health and Human Services (HSS) of a discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug. The bill requires manufacturers to provide (1) 6 months' notice of any discontinuance or planned interruption or adjustment, and (2) notice as soon as is practicable after becoming aware of such an interruption or adjustment in the case of any other interruption or adjustment. The bill defines the adjustments for which a manufacturer must submit notice, including (1) adjustments related to the supply of raw materials, (2) adjustments to production capabilities, (3) business decisions that may affect the manufacture of the drug, and (4) other adjustments as determined appropriate by the FDA. The bill also enables the FDA to work with drug manufacturers to establish contingency plans for manufacturing interruptions such as raw material shortages, adjustments to production capabilities, and product discontinuations.

The proposed legislation includes provisions that would expand the FDA's authority to require manufacturer notification of shortages and market withdrawals and enhance communication among healthcare providers and stakeholders in the pharmaceutical supply chain about the nature and expected duration of shortages. HOPA will support the legislation that has currently been sent to the Senate Health, Education, Labor, and Pension committee. HOPA has also sent a letter to Senators Klobuchar and Casey in support of the bill's passage. HOPA members' support is critical as we work to ensure patients have access to their pharmacists' medication expertise. The HOPA Legislative Affairs Committee urges our members to support the bill through grassroots support—contact your senators and ask them to cosponsor bill S. 296. 



# Board Update

R. Donald Harvey, PharmD BCPS BCOP FCCP, HOPA President



Member involvement, focused effort, leaders in the profession. These tenets have been an important foundation for HOPA since its inception—ones that we will continue to value during the coming year and well into the future. The board will work to guide our organization toward achieving the goals outlined in the strategic plan. If you haven't already done so, I encourage you to review the plan at [www.hoparx.org/about/default/strategic-plan.html](http://www.hoparx.org/about/default/strategic-plan.html).

## Strategic Plan

Since the annual conference, the board has been working on implementing changes related to the plan's three focus areas: advocacy, pharmacy practice standards, and education.

With the help of the Legislative Affairs Committee, the board is working to develop a strategy for legislative advocacy for our members. One important step in strengthening our advocacy efforts has been to contract with Drinker, Biddle, & Reath—one of the leading firms in Washington, DC. These experts in the field will help us develop a 2012 health policy strategic plan and agenda. During the coming year, we will define the best routes and key areas of engagement in the legislation and regulatory environments. Specifically, HOPA is supporting bill S. 296 in the Senate, the Preserving Access to Life-Saving Medications Act.

We also are advocating with other organizations. With help from the American Society of Clinical Oncology (ASCO), we continue to move forward in adding oral chemotherapy standards to the ASCO/Oncology Nursing Society chemotherapy administration standards and risk evaluation and mitigation strategies (REMS) programs as we broaden our reach and influence in the field. Members' voices are critical to our advocacy efforts. As we define our agenda,

issues such as drug shortages, REMS programs, and healthcare reform are likely to emerge, and we will solicit your help in collectively voicing and advancing our profession's goals and capabilities.

Efforts in developing hematology/oncology pharmacy practice standards also are underway; the first guideline the Standards Committee will tackle will focus on investigational drug service. Educational efforts also are beginning—a member-driven submission process for educational sessions and speakers has been implemented for this year's conference.

## Foundation

Research centered on pharmacy continues to be a focus for HOPA. A strategic planning session was held in June with foundation chair Susan Goodin leading the discussion and efforts. The foundation will support research efforts by hematology/oncology pharmacists aimed at optimizing the care of individuals affected by cancer. Research education, providing financial support in the form of grants, and acquiring resources will be areas of strategic development.

## Industry Relations Council

Our industry partners support the mission of HOPA, and we are proud to welcome Eisai, Bristol-Myers Squibb, and Millennium as our founding members of the Industry Relations Council (IRC). I would like to thank them for their support, and the board looks forward to working with them through the IRC. For more information about the IRC, visit [www.hoparx.org](http://www.hoparx.org).

Finally, please consider nominating a colleague or mentor for one of the HOPA membership awards. And don't forget to vote for future board members when the 2012–2013 ballot opens on November 1. The future of HOPA depends on the willingness, experience, and commitment of our members to serve in leadership roles. Our members are our greatest resource, and the board welcomes your input and needs your voice. Thanks to our diverse members, we continue to grow our organization and think and act strategically for now and the future of our profession. 

## BCOP Recertification Committee

Ryan Bookout, Chair

Debbie Blamble, Vice Chair

Six Oncology Pharmacy Specialty Sessions for BCOP recertification were offered at the 2011 HOPA Annual Conference in Salt Lake City, UT, on March 23–26. The topics presented were

- “Updates in the Treatment of Metastatic Breast Cancer” by Michael Berger, PharmD BCOP
- “The Heart of the Matter: When Targeted Cancer Therapies Cause Off-Target Toxicities” by Courtney Bickford, PharmD BCPS
- “Chronic Lymphocytic Leukemia” by Ashley Morris Engemann, PharmD BCOP

- “Castration-Resistant Prostate Cancer” by Rebecca Greene, PharmD BCOP
- “Immunizations in Cancer Patients: Recommendations for Vaccine Preventable Diseases in the Immunocompromised Population” by Kamakshi V. Rao, PharmD BCOP CPP
- “Germ Cell Tumors: Beyond BEP” by Kellie Jones, PharmD BCOP.

If you attended all six sessions, you are eligible to complete the examination to receive BCOP recertification credit. You should have received an e-mail from HOPA after the meeting that includes a link to the examination. If you have not received this e-mail, please contact [info@hoparx.org](mailto:info@hoparx.org). The examination must be successfully completed by 11:59 pm CST on December 31, 2011, to receive BCOP recertification credit.

If you missed the HOPA Annual Conference, the six Oncology Pharmacy Specialty Sessions will be presented twice more. The 2011 American College of Clinical Pharmacology Annual Meeting is being held in Pittsburgh, PA, on October 16–19. The oncology sessions will be offered in two parts: part 1 will take place on October 18 from 1:30–4:30 pm and part 2 will be on October 19 from 9 am–noon. The sessions will be repeated for the third and final time at the 2011 American Society of Health System Pharmacists Midyear Clinical Meeting in New Orleans, LA, on December 4–8. Again, the oncology sessions will be offered in two parts. On Tuesday, December 6, part 1 will be offered from 8–11 am and part 2 will be offered from 2–5 pm. If you attend all six sessions at either meeting, you will receive an e-mail with a link to the examination to claim BCOP recertification credit. Again, the examination must be successfully completed by 11:59 pm CST on December 31, 2011, to receive BCOP recertification credit.

The BCOP Recertification Committee would like to thank the faculty of the Oncology Pharmacy Specialty Sessions for all of their hard work in providing these continuing education opportunities that support BCOP recertification. As members can appreciate, presenting one of these sessions requires a tremendous time commitment on the part of the speaker. We have been fortunate to have such dedicated faculty presenting the 2011 sessions.

The BCOP Recertification Committee has already begun planning for the 2012 Oncology Pharmacy Specialty Sessions. The topics have been determined, and we are currently finalizing speakers. We would like to thank all of the members who took the opportunity to complete an application in response to the call for speakers. The topics for 2012 are pharmacoeconomics of cancer (including quality of life), lung cancer, bone health, esophageal and gastric cancers, ten topics in lymphoma (focus on cutaneous and T-cell), and treating cancer in the adolescent and young adult population. We are optimistic that we will have speakers selected shortly and will begin development of the sessions. Thanks in advance to all of the BCOP Recertification Committee members who have volunteered to be a part of this process for the upcoming year.

## CE Accreditation Committee

*Carol Balmer, Chair*

*Jolynn Sessions, Vice Chair*

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The 2011–2012 year brings the implementation of a newly reorganized administrative structure for continuing pharmacy education (CPE) within HOPA. In the past, all CPE administrative and learning activity review functions were combined within one committee, the CPE Committee. Some members served only as reviewers, others had administrative roles, and others balanced both areas of responsibility. The committee chair also served as the Accreditation Council for Pharmacy Education (ACPE) administrator of record, with responsibilities for all ACPE reports and submissions.

The new structure, approved by the Board of Directors last year, divides these responsibilities among a CPE Accreditation Committee, a CPE Review Panel, and HOPA's management company, AMC.

The CPE Accreditation Committee is responsible for ensuring full compliance with all ACPE standards for each CPE activity, developing or revising policies and standard operating procedures, training

reviewers, and working with other committees on all CPE-related issues. Some specific initiatives for the 2011–2012 year include implementing the CPE Monitor program and developing standard operating procedures for enduring programs. The CPE Accreditation Committee consists of representatives from the Education and Program Committees and the general membership.

The CPE Review Panel is primarily responsible for performing content and ACPE compliance reviews for every CPE activity. This review determines whether the learning activity meets ACPE standards so that ACPE credit can be issued for the activity. Members also serve as field testers for all home-study activities to help determine the number of contact hours to be assigned to each activity. The panel has 10–12 members who primarily represent HOPA's general membership. The Review Panel and the Accreditation Committee share the same chair and cochair. Two CPE Accreditation Committee Members also serve on the panel.

Lori Goodnow, Director of Education, serves as the official ACPE administrator of record. She submits all HOPA learning activities to ACPE to obtain CPE activity numbers, creates and issues statements of credit, processes results of learner assessments and program evaluations, and submits all required reports to ACPE.

We look forward to working within the new structure to continue HOPA's strong record of providing excellent accredited CPE opportunities for HOPA members.

## Education Committee

*Helen Marshall, Chair*

*Laura Wiggins, Vice Chair*

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The Education Committee has been busy planning the 2012 Oncology Boot Camp. The popular Boot Camp is back this year and will again be offered prior to the start of the HOPA Annual Conference. Programming this year will focus on the basics surrounding the use of targeted therapies in hematology/oncology. In other educational offerings, two new programs have been made available on HOPA University since the annual conference. These are "Update on Drug Targets and Cell Signaling Pathways" (released April 15) and "Myelodysplastic Syndromes: The Evolving Treatment Landscape" (released June 10). Additional programs remain available for continuing education, and programs from the annual conference should be available in the near future. The Education Committee will continue to work on bolstering HOPA U's offerings as well as the Hot Topics Webinar Series.

The 2011–2012 Education Committee members are Jayde Bednarik, Dan Bestul, Anthony Jarkowski, Sara Kim, Mimi Lo, Michael Newton, Dan Sageser, Judith Smith, and Amy Williams. We appreciate the help of our Board Liaison, Lisa Holle.

## Legislative Affairs Committee

*Ali McBride, Chair*

*Tim Tyler, Vice Chair*

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The HOPA Legislative Affairs Committee's objective is defining issues that are affecting our clinical practitioners, managers, and patients in particular. The focus of our work has been to assist our members with issues that so often affect our patients. With healthcare reform



and policy changes always beckoning at our door, the Legislative Affairs Committee continues to keep tabs on the issues affecting our practice landscape in oncology. With the development of the new HOPA Strategic Plan, HOPA has turned its attention to the legislative issues most salient to our members. HOPA has hired Drinker, Biddle, and Reath (DBR) to develop a legislative strategic plan and health policy agenda. The plan will include an evaluation of policy issues in which HOPA may provide leadership in specific policy issues related to oncology care. DBR will survey members to identify specific legislative and regulatory areas and assess HOPA political assets with respect to political relationships and policy thought leaders who may assist in the advocacy process. We look forward to the relationship with DBR and expect a focused venue in which we will align our future policy and advocacy agenda. During the interim, the Legislative Affairs Committee continues to work on three significant issues affecting clinical oncology practice: drug shortages, risk evaluation and mitigation strategies (REMS), and oral chemotherapy.

The national medication shortage crisis, specifically oncology and supportive care medications, has affected patient care at almost every institution providing chemotherapy. Numerous practice sites have had to turn away patients or delay patient care. HOPA has been intimately involved with these issues and was present as a stakeholder at the American Society of Health-System Pharmacists coconvened drug shortage summit in 2010. Working with other organizations, agencies, and manufacturers, HOPA described the dire circumstances regarding oncology drug shortages that have increased in incidence during the past 5 years. One topic discussed during the meeting was the increased need for U.S. Food and Drug Administration (FDA) enforcement and communication regarding drug shortages by manufacturers. The Senate and the House have produced two bills (S. 287 and H.R. 2245) focused on increasing the authority of the FDA in developing communication efforts between manufacturers when a drug shortage occurs, enhancing the power of the FDA in issuing penalties to manufacturers who fail to report drug shortages, and changing the definition of medical necessity. The bill would also direct the FDA to provide up-to-date public notification of any shortage situation and the actions the agency would take to address them. The HOPA Legislative Affairs Committee has written letters of support for these bills and will continue to voice HOPA's opinion regarding drug shortages.

REMS are a particularly important issue for oncology and for HOPA members. The specific strategy a REMS program employs will vary but may include providing a medication guide, a patient package insert, a communication plan, elements to ensure safe use, and an implementation system. All REMS programs must contain a timetable for assessment. Pharmacists and pharmacies are aware of the increased REMS requirements needed for enrollment of patients into specific programs. They will likely have to complete educational programs or comply with certain procedural changes to acquire the necessary certification to dispense particular medications. The Legislative Affairs Committee has worked on a Q&A for the APPRISE program that will address members' concerns regarding erythropoiesis-stimulating agents and REMS implementation; this should be available on the HOPA website in the near future. In addition, Niesha Griffith, Phil Johnson, and Lisa Holle have been invited to participate in a workshop sponsored by the American Society of Clinical Oncology to discuss issues related to the

FDA's oncology REMS program. The information developed from this workshop will hopefully address REMS implementation and issues related to their implementation in practice.

Oral chemotherapy cost and safety continue to be persistent issues with our patient population and workplace. Although the increasing number of available oral chemotherapies offers many cancer patients a more convenient and less invasive treatment option compared with infusion therapy delivered in a clinical setting, oral drugs also require a new model for patient education, monitoring, and support. Financial considerations also figure prominently into the oral chemotherapy equation. In addition to a significant difference between the cost of oral chemotherapy and traditional infusion, patients obtaining a prescription for oral chemotherapy from a pharmacy are required to pay when the prescription is filled. Infusion patients, on the other hand, provide insurance information up front, receive treatment, and typically pay a balance due at some point after insurance claims are processed. The HOPA Legislative Affairs Committee is advocating for support of patient care and oral chemotherapy parity for patients. Several state legislatures have already passed or are considering parity legislation that would require state-regulated payers to cover oral chemotherapy drug cost sharing as intravenous/injected drug. HOPA will evaluate this process as other states appraise or adopt similar legislation.

The HOPA Legislative Affairs Committee continues to work on numerous issues that may have future implications after healthcare reform goes into effect. We continue to voice the concerns of our membership and solicit your ideas and concerns regarding clinical pharmacy issues, practice management, and patient care. As we work with DBR this year, we hope to develop a succinct methodology to identify and evaluate topics as priorities for HOPA's advocacy efforts. Focusing on these topics, we hope to bring our members' concerns to the political forefront of oncology pharmacy-related issues. This year will certainly be one of change, and we look forward to sharing the journey with our members.

## Membership Committee

*Meredith Moorman, Chair*

*Jennifer LaFollette, Vice Chair*

The HOPA Membership Committee would like to remind members about the new membership program—the New Colleague Recruitment Program. From now until December 1, 2011, for every member you recruit, you will receive the following benefits:

- one free month of membership added to your existing membership
- one entry into a drawing to win one of the following three prizes:
  1. complimentary registration to the 2012 Annual Conference in Orlando, FL
  2. a travel grant for \$250 to the 2012 Annual Conference in Orlando, FL
  3. one free year of HOPA membership.

Please note that complimentary registration cannot be transferred to another member or substituted for another year and that the travel grant cannot be transferred to another member and will be distributed in Orlando at the 2012 Annual Conference.

To get credit for your member referrals, please make sure that your name appears on the paper application submitted by the new member in the “recruited by” section. If the new member joins HOPA via online registration, an e-mail must be sent to [info@hoparx.org](mailto:info@hoparx.org) by your referral noting your recruitment. There is no limit to the number of free months of extended membership.

In addition to this new program, many of HOPA’s previous membership discounts are still available. These include

- a 25% discount for new members who join for 2 years
- a 5% discount for current members who renew for 2 years
- group membership discounts for institutions with 10 or more members.

For more information, contact HOPA at 877.467.2791.

Help your colleagues realize the benefits that HOPA can provide, such as online continuing education via HOPA U and the HOPA Annual Conference. Encourage them to visit the HOPA website at [hoparx.org](http://hoparx.org) and join today! We look forward to working with HOPA members and committees to help grow the organization throughout the year!

## Nominations and Awards Committee

*Laura Jung, Chair*

*Jane Pruemer, Vice Chair*

The Nominations and Awards Committee is ramping up for another successful year! To better accommodate the timing of the 2012 HOPA Annual Conference in March, HOPA board elections are taking place earlier this year.

Nominations for the following HOPA Board positions opened on June 30:

- President-Elect (3-year term)
- Treasurer (2-year term)
- Member-At-Large (2-year term)—two positions are available.

The deadline for nominations was August 2, 2011. Elections will open November 1 and close December 1.

Nominations for the HOPA awards also opened on June 30. HOPA awards are presented to HOPA members who have demonstrated outstanding achievement in their field.

The HOPA Award of Excellence recognizes a HOPA member who has made a significant, sustained contribution to or provided excellent leadership in developing or supporting hematology/oncology pharmacy.

The HOPA New Practitioner Award recognizes a HOPA member early in his or her career who has made a significant contribution to developing or supporting clinical hematology/oncology pharmacy services.

The HOPA Hematology/Oncology Technician Award recognizes a HOPA technician member who demonstrates excellence in his or her work and a commitment to hematology/oncology pharmacy practice in an organized healthcare setting.

The HOPA Basic Science and Clinical Research Literature Award recognizes a scientific article describing hematology/oncology basic

science or translational research or clinical trials evaluating drug efficacy or safety published by a HOPA member between November 2010 and November 2011. Examples of eligible articles include basic research studies (i.e., cellular, genetic, or animal studies), clinical trials, or pharmacokinetic or pharmacodynamic studies.

The HOPA Oncology Pharmacy Practice Literature Award recognizes an article other than scientific research that contributes to the betterment of the hematology/oncology pharmacy profession and describes innovations in community, hospital, or healthcare system hematology/oncology pharmacy practices published by a HOPA member between November 2010 and November 2011. Eligible articles describe any aspect of professional practice including administrative, managerial, technological, pharmacoeconomics, new practice models, clinical services, or drug use control.

All nominees must be HOPA members in good standing and may be nominated by any HOPA member. To view a description of each award or to nominate colleagues for specific HOPA awards, visit [www.hoparx.org](http://www.hoparx.org). The deadline for nominations is November 15, 2011. Awards will be presented at the HOPA 2012 Annual Conference in Orlando, FL.

If you have any questions regarding HOPA board member elections or the HOPA awards nominations, please contact Mary Beth Benner at [mbbenner@connect2amc.com](mailto:mbbenner@connect2amc.com).

## Program Committee

*Jill Rhodes, Chair*

*Larry Buie, Vice Chair*

The Program Committee is hard at work planning the HOPA 8th Annual Conference! We would like to thank the 2011 conference attendees for providing feedback on the speaker and meeting evaluations. This information is valuable as we work toward developing the educational content for the next annual conference.

The committee is currently in the process of selecting a dynamic individual to provide our keynote address, which will focus on a theme of survivorship, to kick off the conference. The conference agenda will be similar to previous conferences, however there will be some exciting changes, including

- an increased variety of breakout sessions
- a clinical pearls session
- a practice session panel
- a call for speakers for the 2012 annual program.

New for this year, the Program Committee created a call for speakers for the 2012 Annual Conference. HOPA members were invited to submit proposals for breakout sessions as well as a brand new clinical pearls session. This is a terrific opportunity for HOPA members to share their expertise and knowledge while enhancing the quality of education provided at the annual conference. A Session Proposal Task Force reviews submissions for selection and inclusion in the program agenda. In addition, an all-new Practice Sessions Panel will be held to discuss the significant practical issues that oncology pharmacists face today. The educational programming is being developed in conjunction with other key HOPA committees to provide a wide variety of offerings that meet the diverse needs of our members.



In addition to the overall agenda for the 2012 HOPA Annual Conference, the Program Committee is coordinating the research abstract submission and selection process. A research task force has been hard at work streamlining the research abstract submission and selection process. Abstracts accepted in the completed research category will be published in the *Journal of Oncology Pharmacy Practice*. Poster abstract submissions are now being accepted online. The submission deadline for completed research is October 10, 2011, and the submission deadline for Trainee Research-in-Progress is January 4, 2012. For more information on criteria for abstract selection and submission, please visit the website at <http://hopa.confex.com/hopa/2012/trainee/cfp.cgi>.

The HOPA 8th Annual Conference will take place March 21–24, 2012, in Orlando, FL. Please continue to visit the HOPA website to view conference updates and registration information as it becomes available.

### Publications Committee

*Lisa Savage, Chair*

*Brandy Strickland, Vice Chair*

The HOPA Publications Committee is off to a busy start. In addition to organizing the publication of this issue of the newsletter, the committee has been hard at work developing an editorial calendar and the concept of rotating section editors.

- In addition to outlining the editorial process for members, an electronic calendar was compiled to include dates of relevant organizational conferences (e.g., HOPA, American Society of Clinical Oncology, American Society of Hematology, American Society of Blood and Marrow Transplantation) as a means of proactively obtaining information to include in the newsletter.
- Editorial categories were developed to allow committee members to be involved in their areas of interest as well as rotate and serve as back-up reviewers and writers for other areas.

- Categories include hematology, solid tumors, drug updates, operations, committee updates, and pediatrics.
- Section editor roles include idea generation, identification of authors, writing (if desired), and editing articles for content.

Both enhancements are designed to continue efficient and timely newsletter development and distribution.

I am also happy to report that more than 75 people have volunteered to assist with the newsletter! We are looking forward to working with you, and, as always, if you have any ideas, suggestions, or topics for the newsletter, please e-mail us at [info@hoparx.org](mailto:info@hoparx.org).

### Standards Committee

*LeAnne Kennedy, Chair*

*Barry Goldspiel, Vice Chair*

The HOPA Standards Committee has begun to review the standard operating procedure for guideline development that was recently approved by the HOPA board. We have received approval from the board to move forward with standard development related to investigational drug services. This will be our first official standard that HOPA will review and develop. We are excited to announce that HOPA has been approached by the Oncology Nursing Society and the American Society of Clinical Oncology to assist in the development of standards related to chemotherapy administration. We are excited that other national organizations are recognizing HOPA and would like to have us work collaboratively with them. As we move forward, please keep visiting the HOPA Volunteer Activity Center to keep HOPA informed of how you want to be involved. You may be asked to help with deciding which standards we should target next or even to help develop, write, or review the proposed standards. 

## American Society of Clinical Oncology: Annual Meeting Summary

*R. Donald Harvey, PharmD BCPS BCOP FCCP, HOPA President*

The theme of the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting was “Patients. Pathways. Progress.” The clinical trial data presented in Chicago at the meeting certainly echoed those sentiments. Although summarizing the entire meeting in this article is beyond this writer’s skill, I will try to encapsulate key clinical advances that occurred in areas not typically highlighted by ASCO—breast cancer prevention and melanoma.

### Presidential Address

Patients come first. ASCO President George W. Sledge, Jr., MD, emphasized the need for clinicians to continue nurturing their “compassion for our fellow beings and our belief in their essential dignity.” Patients must be the primary focus and the source of inspiration for clinicians devoted to oncology, according to Sledge. His message

resonates with HOPA’s mission and our core purpose of supporting pharmacy practitioners and promoting and advancing hematology/oncology pharmacy to optimize the care of individuals affected by cancer.

### Clinical Trial Results

Melanoma was a focus of the annual meeting. Clinical trial data regarding agents targeting novel molecular drivers and events generated interest throughout the meeting and in the press. Both ipilimumab (anti-CTLA4 monoclonal antibody) and vemurafenib (PLX4032, a tyrosine kinase inhibitor targeting the V600E mutation in the BRAF gene) demonstrated improved survival in patients with melanoma and were widely reported on.

For ipilimumab, this was the second phase 3 trial to show an overall survival (OS) benefit for the drug. Patients were randomized equally to receive ipilimumab 10 mg/kg plus dacarbazine (850 mg/m<sup>2</sup>) or dacarbazine and placebo. OS was significantly longer in the ipilimumab group than in the placebo group (11.2 vs 9.1 months; hazard ratio [HR] for death, 0.72;  $p < .001$ ), and some responses were durable to 3 years with survival rates of 20.8% and 12.2%, respectively.

Data from a phase 3 trial were also reported for vemurafenib. Patients were randomly assigned to receive either vemurafenib (960 mg orally twice daily) or dacarbazine (1,000 mg/m<sup>2</sup> intravenously every 3 weeks). At 6 months, estimated OS was 84% (95% CI, 78–89) in the vemurafenib group and 64% (95% CI, 56–73) in the dacarbazine group. There is no median OS in the study yet because the data have not matured. Approximately half of patients with melanoma have the V600E mutation. Resistance concerns are real with vemurafenib, however the improvements in OS outweigh fears of development.

In breast cancer, prevention with the aromatase inhibitor exemestane was shown to reduce the risk of invasive breast cancer occurrence in postmenopausal women at increased risk of developing breast cancer compared to placebo in the MAP3 trial of more than 4,500 patients.

With a median 35 months follow-up, 11 patients treated with exemestane compared with 32 in the placebo group developed breast cancer (annual incidence, 0.19% vs. 0.55%; hazard ratio, 0.35; 95% CI, 0.18–0.70;  $p = .002$ ). Adverse events occurred in 88% of the exemestane group and 85% of the placebo group ( $p = .003$ ) with no significant differences between the two groups in terms of skeletal fractures, cardiovascular events, other cancers, or treatment-related deaths. Further study is required to determine how exemestane compares with the two agents approved for prevention—tamoxifen and raloxifene.

Imatinib data in high-risk adjuvant patients with gastrointestinal stromal tumors (GIST) were also presented, demonstrating that 3 years of therapy improved recurrence-free survival (RFS) and OS compared with standard 1-year adjuvant therapy. Patients who received 400 mg of imatinib orally for 36 months were 54% less likely to experience recurrence (hazard ratio, 0.46; 95% CI, 0.32–0.65;  $p < .0001$ ) compared with patients who received the drug for 12 months.

Overall, the key clinical trial data from this year's ASCO meeting significantly advanced our knowledge and will have direct application to our patient's care. 

## Introducing HOPA's New Colleague Recruitment Program

HOPA members can earn an additional 1-month extension on their membership year for each member they recruit. In addition, participants will receive one entry into a drawing for additional prizes.



Hematology/Oncology  
Pharmacy Association



Visit the Membership section of the HOPA website for complete details. [hoparx.org/membership](http://hoparx.org/membership)



# Drug Updates

## Abiraterone (Zytiga™)

**Class:** Antiandrogen (inhibitor of extragonadal testosterone production)

**Indication:** Castration-resistant prostate cancer

**Dose:** 1,000 mg PO daily

**Serious adverse effects:** Hypertension, edema, electrolyte abnormalities, hypertriglyceridemia, cardiac dysrhythmias, elevated liver function tests, heart failure

**Drug interactions:** Inhibitors and inducers of CYP3A4; substrates of CYP1A2, CYP2C19, CYP2C9, and CYP2D6

## Abiraterone in the Treatment of Castration-Resistant Prostate Cancer

Lisa Lohr, PharmD BCOP BCPS

Oncology Clinical Pharmacist/MTM Provider

Masonic Cancer Center, University of Minnesota–Fairview, Minneapolis, MN

Until recently the treatment of castration-resistant prostate cancer (CRPC) consisted of chemotherapy regimens of docetaxel/prednisone and mitoxantrone/prednisone, along with hormonal manipulations such as antiandrogens, antiandrogen withdrawal, or ketoconazole. Recent studies have demonstrated the effects of cabazitaxel (Jevtana®) and sipuleucel-T (Provenge®).<sup>1</sup> A new medication, abiraterone (Zytiga®), was recently approved by the FDA for the treatment of CRPC and has a unique mechanism of action.

Several mechanisms might be responsible for the progression of prostate tumors after medical or surgical castration, including androgen receptor mutations, androgen receptor amplification, alternate sources of androgen production, or local production of androgens. In some patients with CRPC, extragonadal production of testosterone can continue in the adrenal glands and the tumor tissue itself, which then can fuel the growth of the prostate cancer tissue.<sup>2-4</sup> An enzyme called CYP17 is a rate-limiting step in the synthesis of testosterone, especially in the adrenal glands and tumor tissue. CYP17 catalyzes reactions involving 17 $\alpha$ -hydroxylase and C17-20-lyase, which transforms pregnenolone and progesterone into dihydroepiandrosterone (DHEA) and androstenedione, precursors to androgen production in the peripheral tissues.<sup>2-4</sup>

Abiraterone is an irreversible and selective inhibitor of CYP17, which then reduces the testosterone produced in the adrenal glands and tumor tissue that might lead to tumor growth.<sup>2-4</sup> Abiraterone does not cause general adrenal suppression, however the inhibition of CYP17 may result in increased adrenocorticotropic hormone level, which may lead to a relative mineralocorticoid excess. This can be suppressed with low-dose corticosteroid administration.<sup>2,3,5</sup>

Abiraterone is rapidly absorbed by the oral route and then deacetylated to its active form.<sup>4,5</sup> Administering abiraterone with food was

found to significantly increase the C<sub>max</sub> and AUC; it is recommended that it be administered on an empty stomach.<sup>4,5</sup> Abiraterone is highly protein bound and shows a very large volume of distribution.<sup>5</sup> The half-life is approximately 10–12 hours but is longer in patients with poor liver function. The medication is hepatically metabolized via CYP3A4 and SULT2A1<sup>4,5</sup> and is excreted in the stool, mostly as inactive metabolites.<sup>5</sup>

One group of researchers<sup>6</sup> studied the use of abiraterone (1,000 mg PO daily) in a two-stage, phase 2 trial. Forty-seven patients with CRPC (previously treated with docetaxel) were enrolled in this multicenter trial. The median age of patients was 67 years and the median baseline prostate-specific antigen (PSA) was 403 ng/mL. Most patients had bone and soft tissue metastases; all patients had been treated with hormonal agents, and some had also been treated with chemotherapy agents in addition to docetaxel. The primary endpoint was the proportion of men attaining a  $\geq 50\%$  decline in PSA at least once during the study. This primary endpoint was attained in 51% of patients. In addition, a  $\geq 30\%$  decline in PSA was seen in 68% of men, and a  $\geq 90\%$  decline was seen in 15% of patients. The median time to progression of the PSA level was 24 weeks. The most commonly reported side effect was hypokalemia. Other reported side effects included nausea, constipation, fatigue, edema, anorexia, hyperglycemia, headache, and hypertension. Grade 3 toxicities reported were nausea, fatigue, hypokalemia, and anorexia. There were no reported grade 4 toxicities. The authors concluded that abiraterone showed significant activity.

Similar to the previously cited study, another group of researchers conducted a phase 2 study to determine the effects of abiraterone on patients with CRPC with progressive disease after being treated with docetaxel.<sup>7</sup> Abiraterone was administered at a dose of 1,000 mg PO daily along with prednisone 5 mg PO twice daily. As in the previous study, the primary outcome was the proportion of patients experiencing a  $\geq 50\%$  decline in PSA levels. In this study, the median baseline PSA level was 190 ng/mL. Overall, 43% of patients met the  $\geq 50\%$  decline endpoint. In addition, 47% of men achieved a  $\geq 30\%$  decline and 16% of men had a  $\geq 90\%$  PSA decline. The response rate seemed to be higher in men who had not been previously treated with ketoconazole (a nonselective CYP17 inhibitor.) Also, 28% of patients showed an improvement in performance status, with 7% showing a decline in performance status. One patient (2%) experienced grade 3 fatigue. There were no grade 4 toxicities reported in this trial. The most common adverse effects were nausea, vomiting, and fatigue. Edema, hypertension, and hypokalemia were occasionally noted, but the frequency was low due to the administration of prednisone.

The results of a large, placebo-controlled, phase 3 trial were recently published.<sup>8</sup> This group of researchers enrolled 1,195 patients with CRPC who had progressive disease on docetaxel. The patients were randomized 2:1 to receive abiraterone 1,000 mg PO daily or placebo. All patients received prednisone 5 mg PO twice daily. The primary endpoint was overall survival. The median age of the patients was 69 years, with most having bone or nodal involvement. The baseline PSA level was 129 ng/mL in patients treated with abiraterone, and 138 ng/mL in the

placebo group. As the primary endpoint, the survival of patients in abiraterone group was longer (14.8 months) compared with the placebo group (10.9 months;  $p < .001$ ). In addition, time to PSA progression was longer (10.2 vs 6.6 months;  $p < .001$ ); progression-free survival (5.6 vs 3.6 months;  $p < .001$ ) and proportion of men achieving a  $\geq 50\%$  decline in PSA levels favored the abiraterone group (29% vs 6%;  $p < .001$ .) The most common grade 3–4 adverse effects reported were anemia, fatigue, back pain, and bone pain.

The most common overall toxicities reported were anemia, fatigue, back pain, nausea, constipation, arthralgia, bone pain, and fluid retention. Hypokalemia (17%) and hypertension (10%) were not commonly reported. The authors concluded that abiraterone plus prednisone prolonged survival in these heavily pretreated CRPC patients.

Available as 250-mg tablets, the usual dose of abiraterone is 1,000 mg PO daily taken on an empty stomach (2 hours before or 1 hour after a meal)<sup>5</sup> in conjunction with prednisone 5 mg PO BID. Those with moderate hepatic impairment (Child-Pugh B) should receive only 250 mg PO daily. No adjustment is needed for patients with mild hepatic impairment, and abiraterone is not recommended in those with severe hepatic impairment. If a patient develops hepatic impairment during therapy, abiraterone should be held until hepatic function improves. It may be possible to restart therapy at a lower dose.<sup>5</sup>

Several drug interactions are possible with abiraterone. It is an inhibitor of CYP2D6 and would be expected to increase the blood levels of 2D6 substrates. It should be avoided with medications with a narrow therapeutic index that are CYP2D6 substrates (e.g., carvedilol, propafenone, some tricyclic and SSRI antidepressants, haloperidol, flecainide, promethazine). Abiraterone is itself metabolized by CYP3A4. Agents that are strong CYP3A4 inhibitors haven't been studied but would be expected to increase the blood levels of abiraterone (i.e., increase toxicity). Examples of CYP3A4 inhibitors are clarithromycin, amiodarone, itraconazole, voriconazole, ketoconazole, saquinavir, nelfinavir, and ritonavir. In addition, medications that are strong CYP3A4 inducers should decrease the blood levels of abiraterone (i.e., decrease effectiveness). Examples of CYP3A4 inducers include carbamazepine, rifampin, Phenobarbital, and phenytoin. Abiraterone is also a strong inhibitor of CYP1A2 and a moderate inhibitor of CYP2C9, 2C19, and 3A4/5.

The most common adverse effects reported include hypertriglyceridemia, joint swelling or discomfort, myalgia, edema, flushing, hypokalemia, and hypophosphatemia. Serious, but less common, adverse effects are hypertension, cardiac dysrhythmias, heart failure, adrenal insufficiency, and elevations of transaminases and bilirubin.

Abiraterone is a significant advance in the treatment of CRPC, showing a higher response rate and survival compared with placebo. This is an orally available medication that is fairly well tolerated and doesn't have the usual chemotherapy-induced side effects. There are possible drug interactions, and concurrent medications should be screened for problems. In addition to abiraterone, other agents (cabazitaxel and sipuleucel-T) have been approved for the treatment of CRPC. Additional studies will be needed to delineate the roles of each of these agents.

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# Drug Updates

## Vandetanib (Caprelsa®)

**Class:** Tyrosine kinase inhibitor

**Indication:** Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease

**Dose:** 300 mg PO daily

**Dose modifications**

- Moderate (creatinine clearance >30 to <50 mL/min) to severe (creatinine clearance <30 mL/min) renal impairment: Reduce dose to 200 mg PO daily.
- Corrected QT interval, Fridericia (QTcF) > 500 ms: Interrupt therapy until QTcF returns to < 450 ms, then resume at reduced dose.
- Any grade ≥3 toxicity: Interrupt therapy until toxicity resolves or improves to grade 1, then resume at reduced dose.

**Common adverse effects:** Diarrhea, rash, acne, nausea, hypertension, headache, fatigue, decreased appetite, abdominal pain, hypocalcemia, increased alanine aminotransferase, decreased glucose

**Serious adverse effects:** QT prolongation, torsades de pointes, sudden death, Stevens-Johnson syndrome, interstitial lung disease, ischemic cerebrovascular events

**Drug interactions:** CYP3A4 inducers may alter vandetanib plasma concentrations. No significant interactions were identified between a potent CYP3A4 inhibitor, itraconazole, and vandetanib. Avoid concomitant use of other QT-prolonging agents.

**Caprelsa® Risk Evaluation and Mitigation Strategies**

**(REMS) Program:** Prescribers must enroll. Vandetanib is only available through a restricted distribution program, not at retail pharmacies.

Radiation therapy in select patients has been reported to improve disease-free survival.<sup>7</sup> Adjuvant external beam radiation may be considered in patients with disease extending beyond the thyroid or extensive locoregional lymph node involvement.<sup>5</sup> Conventional chemotherapy has had limited efficacy in MTC and has not been shown to prolong overall survival.<sup>2</sup> Recommended treatment options for patients with unresectable or metastatic disease include vandetanib, dacarbazine-based chemotherapy, radiation therapy, clinical trial, or best supportive care.<sup>5</sup> Sunitinib and sorafenib have demonstrated efficacy in phase 2 trials and may be considered for patients who are not eligible for clinical trials or other therapies.<sup>8,9</sup>

Vandetanib is an oral tyrosine kinase inhibitor. It received U.S. Food and Drug Administration (FDA) approval on April 6, 2011, for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced or metastatic disease. It inhibits multiple tyrosine kinases, including RET, epidermal growth factor receptor (EGFR), and vascular endothelial cell growth factor (VEGF) receptor. The inhibition of multiple tyrosine kinases results in a reduction of tumor-induced angiogenesis, tumor vessel permeability, tumor growth, and tumor metastasis.<sup>10</sup>

The safety and efficacy of vandetanib was evaluated in a randomized, double-blind, phase 3 trial. Patients with unresectable measurable, locally advanced or metastatic hereditary or sporadic MTC were randomized 2:1 to vandetanib 300 mg PO daily or placebo. The primary endpoint was progression-free survival (PFS) and was determined by independent central Response Evaluation Criteria in Solid Tumors (RECIST) assessment. Secondary endpoints included objective response rate (ORR), disease control rate (DCR), and OS.<sup>11</sup>

Three hundred thirty-one patients were enrolled in the study. Patient characteristics were similar in both arms. Ninety-five percent of patients had metastatic disease. There was a statistically significant improvement in PFS with vandetanib treatment over placebo (HR 0.45; 95% CI 0.30–0.69). Median PFS was 19.8 months with placebo and was not reached with vandetanib after 24 months of follow-up.<sup>11</sup> ORR was 44% with vandetanib compared with 1% in patients who had received placebo (OR 5.4; 95% CI 2.99–10.79). All objective responses were partial responses.<sup>10</sup> DCR was also significantly improved in patients who received vandetanib (OR 2.64; 95% CI 1.48–4.69). At the time of analysis, 15% of patients randomized to vandetanib had died, and there was no difference in OS.<sup>11</sup>

The most common adverse reactions (>20%) of any grade associated with vandetanib therapy were diarrhea, rash, acne, nausea, hypertension, headache, fatigue, decreased appetite, and abdominal pain. The most frequent grade 3–4 toxicities included diarrhea (11%), hypertension (9%), and QT prolongation (8%). Adverse reactions that led to the discontinuation of therapy in >1 patient included asthenia, fatigue, rash, arthralgia, diarrhea, hypertension, prolonged QT interval, increase in creatinine, and pyrexia.<sup>10</sup>

Vandetanib can cause QT prolongation, and there are reports of torsades de pointes and sudden death. Due to the risk of QT prolongation, electrocardiograms (ECGs), electrolytes (potassium, calcium,

## Vandetanib for Medullary Thyroid Cancer

Erika Gallagher, PharmD BCOP

It is estimated that 48,020 new cases of thyroid cancer will be diagnosed in the United States in 2011. Thyroid cancer is three times more common in women than in men and is the fifth most common malignancy diagnosed in women.<sup>1</sup> Medullary thyroid carcinoma (MTC) is a malignancy of the neuroendocrine parafollicular C cells of the thyroid and accounts for 5%–8% of all thyroid cancers.<sup>2</sup> MTC occurs as a hereditary and sporadic form. Mutations of the rearranged during transfection (RET) proto-oncogene are present in hereditary MTC and 30%–50% of sporadic MTC.<sup>2,3</sup>

The primary therapy of MTC is total thyroidectomy.<sup>4,5</sup> Ten-year overall survival (OS) after surgical resection in all stages of MTC is 69%.<sup>6</sup>

and magnesium), and thyroid-stimulating hormones should be obtained at baseline, 2–4 weeks and 8–12 weeks after initiation of vandetanib therapy, and every 3 months thereafter. Vandetanib therapy is contraindicated in patients with congenital long QT syndrome. Electrolyte abnormalities should be corrected prior to the initiation of therapy. Concomitant therapy with QT-prolonging drugs should be avoided (i.e., amiodarone, 5-HT<sub>3</sub> antagonists). If therapy with other QT-prolonging drugs is necessary, ECGs should be obtained more frequently. Electrolytes and ECGs should be monitored more frequently if diarrhea occurs. Severe skin reactions, Stevens-Johnson syndrome, and interstitial lung disease have also been reported in patients receiving vandetanib therapy.<sup>10</sup>

The recommended dosing of vandetanib is 300 mg orally once daily with or without food. A dose reduction to 200 mg once daily is recommended in the setting of moderate to severe renal impairment. If grade 3 or greater toxicities or a QT interval of greater than 500 ms using Fridericia (QTcF) occurs, hold therapy until the toxicity is resolved or QTcF is less than 450 ms. Vandetanib can be reinitiated at a reduced dose of 200 mg once daily and can be further reduced to 100 mg once daily if necessary. It is important to note that the median plasma half-life of vandetanib is 19 days, so toxicities may be slow to resolve.<sup>10</sup>

Vandetanib is available as 100-mg and 300-mg tablets. Vandetanib tablets should not be crushed. If a patient is unable to swallow the tablet whole, the tablet may be dispersed in 2 ounces of noncarbonated water. Patients should be counseled on the importance of ECG and electrolyte monitoring and the use of sun protection and sunscreen during therapy and 4 months after discontinuation. They should consult with a healthcare provider before beginning new medications or herbal supplements due to potential drug interactions (i.e., St. John's Wort). Patients may use antidiarrheal medications to treat diarrhea associated with vandetanib, but should contact their healthcare provider if diarrhea is persistent or severe.<sup>10</sup>

Due to reported QT prolongation, torsades de pointes, and sudden death, vandetanib is only available through a restricted distribution program known as the Caprelsa® REMS Program. Vandetanib is not available at retail pharmacies. Prescribers must complete a training program and obtain a certification number prior to prescribing vandetanib. A medication guide should be provided to the patient before therapy is initiated and with each medication refill. All materials for enrollment can be found at the program's website ([www.caprelsarems.com](http://www.caprelsarems.com)).<sup>10</sup>

Unresectable or metastatic MTC is a rare malignancy with no standard therapy. Vandetanib, an oral tyrosine kinase inhibitor, was recently approved by the FDA for the treatment of symptomatic or progressive MTC in patients with unresectable locally advanced or metastatic disease. Vandetanib improved PFS when compared to placebo in patients with unresectable, locally advanced, or metastatic MTC and is the only agent to demonstrate efficacy in this disease in a phase 3 randomized trial. Additional long-term studies are needed to determine the impact of vandetanib on OS.

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## Introducing Your HOPA Team

HOPA's transition to Association Management Center (AMC) has been an exciting and important time in our organization's growth. We thought it would be helpful to introduce some of the people who have been instrumental in this transition and will be responsible for HOPA's day-to-day business and supporting our members as we move forward. During the next few issues of the newsletter, you will meet the enthusiastic and dedicated staff members who make up your HOPA team.



**Susan Floutsakos, Account Manager**

**Q. What is your role with HOPA? What are some of the specific things you do on a daily basis for the association?**

A. I am HOPA's account manager. I work on a variety of tasks for HOPA, including membership issues, payments and refunds, conference planning, working with the Rays of Hope task force to develop the annual conference fundraiser, helping with conference registration, and coordinating and communicating with the board and volunteers about travel and logistics.

**Q. How long have you been involved in association work? With which other associations have you worked?**

A. I started working with HOPA in August 2010. I also work with the Association of Rehabilitation Nurses.

**Q. Where did you grow up?**

A. I grew up in Glenview, IL, which is where the HOPA national office is located. I began my education at the University of Wisconsin in Whitewater, then studied abroad at the University of Copenhagen in Denmark, and graduated from Southern Illinois University in Carbondale with a degree in communications.

**Q. What is your favorite thing to do in your spare time?**

A. I love photography and also love shopping with my 21-year-old daughter, Sienna, and going on bike rides with my 12-year-old son, Yorgos.

**Q. What is your favorite aspect of working with associations and members?**

A. I enjoy the relationships I am developing with the volunteers. HOPA would not have the success it has today without all of its dedicated volunteers, and it makes me feel good to be able to provide them with the information they need to continue to be successful.

**Q. What aspect of working with HOPA is most exciting for you?**

A. HOPA is such a young association; it's really exciting to be a part of it and watch it grow! 



# HOPA

## Online Career Center

### Making Connections in Oncology Pharmacy

#### For Job Seekers

Anonymous résumé posting

Create and store multiple online résumés and cover letters

Save searches

Job alerts

#### For Employers

Easy-to-use job posting

Résumé search

Access to active and passive candidates

The next best opportunity for pharmacy job seekers and employers is on [www.hoparx.org](http://www.hoparx.org)

## Introducing Your HOPA Team (continued)



**Nichole Arroyo, Education Administrator**

**Q. What is your role with HOPA? What are some of the specific things you do on a daily basis for the association?**

A. I am HOPA's education administrator. I help speakers and committees prepare for and contribute to the annual conference.

**Q. How long have you been involved in association work? With which other associations have you worked?**

A. I have been involved in association work for 12 years. I have worked with the Association of Rehabilitation Nurses, the Association of Pediatric Hematology/Oncology Nurses, the American Board of Neuroscience Nursing, and the National Association of Professional Organizers.

**Q. How did you get your start working with association?**

A. I started working at AMC (HOPA's management company) when I was 22 years old. I never realized how big the association world really was.

**Q. Where did you grow up?**

A. I grew up on the West Side of Chicago; I've been here all my life.

**Q. What is your favorite thing to do in your spare time?**

A. In my spare time I like to read, but with five kids I can't seem to finish a book!

**Q. What is your favorite aspect of working with associations and members?**

A. My favorite aspect of working with associations is helping to prepare members for the challenges that they face every day.

**Q. What aspect of working with HOPA is most exciting for you? What are you looking forward to accomplishing this year with HOPA?**

A. What's most exciting about working with HOPA is being able to help provide hematology/oncology pharmacists with the education they need or have been looking for. I look forward to putting together a great conference in Orlando, FL. 



# Call for Completed Research and Trainee Research-in-Progress Poster Abstracts

Poster abstract submissions are now being accepted for the 2012 HOPA Annual Conference. You do not have to be a member of HOPA to submit an abstract. Encore presentations are acceptable.

The submission deadline for Completed Research is October 10, 2011.

The submission deadline for Trainee Research-in-Progress is January 4, 2012.

Visit Conference Web Central on the HOPA website ([www.hoparx.org](http://www.hoparx.org)) for more information.

*Please note: For your poster abstract to be accepted, attendance at the meeting is required. Completed research abstracts will be reviewed and selected based on a specific set of criteria.*