ASCO Update

Issues and Challenges for 2012

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Bipartisanship?
Fasten Your Seatbelts

- Drug shortages
- SGR and Payment Reform
- Research funding
ASCO’s 2012 Priorities

• **Drug shortages**
  - Triage immediate problems (e.g., methotrexate)
  - Draw attention to larger issue(s)
  - Advance regulatory and legislative solutions

• **Payment reform**
  - SGR
  - Demonstration proposals

• **QOPI as national standard for reporting in oncology**

• **NIH/NCI funding**
  - Retool messages, develop stories of progress

• **Health Equity**
  – Essential health benefit package
  – Oral parity
Drug Shortages
A Growing Crisis

Source: University of Utah Drug Information Service

New Drug Shortages

Year

Source: University of Utah Drug Information Service

Tripled since 2006
# Shortage Drugs in Oncology (as of March 2012)

- Bleomycin
- Cisplatin
- Cytarabine
- Dacarbazine
- Daunorubicin
- Doxorubicin
- Doxorubicin, liposomal
- Etoposide
- Fludarabine
- Fluorouracil
- Leucovorin
- Mesna
- Methotrexate
- Mitomycin
- Mustargen
- Ondansetron
- Paclitaxel
- Thiotepa
- Vinblastine
Most Recent Crisis

• Early February members reporting no more than 2-week supply

• No alternative for treatment of childhood ALL

• No apparent prospect for increased supply

• Institutions beginning to panic
Why Shortages?

It’s a long list, but in general...
Causes of shortages

- Product Quality issues 42%
- Product discontinuation 18%
- Production/Capacity 18%
- Unavailability of raw material (API) 9%
- Loss of site 5%
- Unavailability of other components 4%
- Other drug shortages 4%

Source: FDA Drug Shortages Program
Economic Issues

- Decreased demand
- Pricing issues
- Move to other—more favorable—product line
- Recalls
- Cost of plant improvements vs. profitability
- Regional issues
- Gray market
- Hoarding
- Unfavorable contract arrangements
One Theory (Among Many)

- MMA 2003 established Medicare reimbursement for injectable drugs under Part B at Average Sales Price (ASP) + 6%

- 6 month lag between submission of ASP data to CMS and revised reimbursement

- Difficult to raise prices more than 6% in any 6 month period leaving little flexibility for prices to adjust to market forces

- Reduced incentive for manufacturers to respond to generic shortages
Impact on Clinical Practice

- Treatment delays and substitutions
- Treatment omissions: Doxil, ara-C and methotrexate in particular
- Setting priorities for who gets treated
- Borrowing from other practices
- Hoarding and gray market profiteering
Impact on Clinical Practice

- Increased patient anxiety
- Increased physician/pharmacist workload
- Decreased practice efficiency
- Decreased treatment effectiveness
- Increased risk of adverse events
- Increased cost of treatment and patient co-pays
Impact on Clinical Research

• Decreased accrual
• Protocol “violations”
• Data confounding
Potential Remedies

- Early notification of potential problems
- Economic incentives
- Alternative sources of shortage drug
- Clinical guidance on alternatives
- Legislation
What is ASCO Doing?

CLINICAL ALERT—LEUCOVORIN SHORTAGE

Why is there a shortage of leucovorin?
There is currently a nationwide shortage of injectable racemic leucovorin, available only as a generic drug and only from two manufacturers in the US (Bedford Laboratories and Teva Pharmaceuticals). According to the FDA, the shortages are due to manufacturing delays; however, the American Society of Health-System Pharmacists (ASHP) reports that Bedford cannot provide a reason for the shortage. Information on current availability of specific vial sizes and expected release dates for others can be found on the FDA website (http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm) and on the ASHP website (http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/DrugShortages/GettingStarted/CurrentShortages/Bulletin.aspx?id=488).

What about using levoleucovorin?
Levoleucovorin is the levo isomeric form of racemic (d,l)-leucovorin, and is the pharmacologically
Raising Awareness

- Briefed Congressional Staff
- Congressional testimony
- Testimony at FDA workshop
- Met with HHS secretary
- Outreach to companies

Dr. Charles Penley testifies at House Energy and Commerce hearing.

ASCO President, Michael Link, MD, briefs Congressional staff on drug shortages.
Partner with Stakeholders

• Joint summit Nov 2010

• Areas of recommendations
  – Regulatory/Legislative (13)
  – Raw Materials/Manufacturing (4)
  – Business/Market (2)
  – Distribution (2)
  – Full list at
    www.ashp.org/drugshortages/summitreport

• Partnered with COG and others
  – Expert commentary
  – Patients/stories
Media Outreach

- USA Today
- Wall Street Journal
- New York Times
- Washington Post
- ABC and NBC News
- CNN
- PBS
- ...and others
Build Congressional Support

Legislation...More on the Way

February 2011
Sen. Klobuchar (D-MN)
Sen. Casey (D-PA)

June 2011
Rep. DeGette (D-CO)
Rep. Rooney (R-FL)
User Fee Act Provisions

• House and Senate PDUFA provisions address drug shortages.

• Require manufacturers to provide 6 months notice to the FDA of discontinuance or disruption in “life sustaining drugs” defined as “life-supporting, life-sustaining, or intended for use in prevention of a debilitating disease or condition,” with some exceptions.

• Authorizes HHS to expedite inspections and reviews based on notifications from manufacturers.

• Establishes a task force to mitigate and prevent shortages through intra and interagency coordination working with stakeholders.

• Requires that the FDA keep records and report annually to Congress including the number and causes of shortages, the steps HHS has taken to resolve the shortage, and a trend analysis.

• Senate bill allows the Secretary of HHS to apply above to biologics through regulation.
Hatch Draft Legislation

• Requires manufacturers to report 6 months in advance of anticipated shortage or discontinuance; asap for interruption.

• Generic injectable products with 4 or fewer active manufacturers would increase from ASP + 6% to Wholesale Acquisition Cost (WAC) and exempted from Medicaid rebates and 340B discounts.

• A manufacturer who steps into a shortage market will be given 5 additional years of exclusivity on any NDA they designate.

• Report in three years to include name of drug, manufacturer and cause selected from list in statute. Report will be available to public.
Moving From Talk to Action

• Call on Congress to convene bipartisan workgroup that will pass legislation in the next 60 days:
  – FDA notification
  – Economic incentives
  – Generic manufacturer user fees to provide FDA resources

• Continue work with coalition

• Advocacy/awareness activities

Dr. Link and other stakeholders at a February 21 press conference held by the Food and Drug Administration to discuss the latest shortage of methotrexate
FDA Initiatives

• Draft Guidance on notification to FDA of issues that may result in drug shortage, issued Feb. 21, 2012

• Expedite review of manufacturing sites

• Expedite review of regulatory submissions

• Identify additional sources of supply or alternate manufacturers

• Exercise regulatory discretion on drug importation or expiration dates

• Assist with contingency planning
Recommended New FDA Initiatives

- Expand FDA authority to **require** confidential manufacturer notification of market withdrawals and manufacturing interruptions six months in advance.

- **Require** manufacturing redundancies as part of the FDA approval process (i.e. multiple manufacturing sites for a sole product or multiple API sources, when available).

- FDA should rely on the inspection results of other foreign regulatory bodies with similar regulatory oversight or use accredited third parties to conduct foreign inspections.
Recommended New FDA Initiatives

• Establish generic user fees to ensure that FDA has resources to review new and supplemental generic drug applications quickly and provide flexibility to allow FDA to use fees as economic incentives for manufacturers.
Physician Payment
The debt hasn’t gone away....even if the “Super Committee” did....
Sustainable Growth Rate (SGR)

- Congress has passed a 10-month patch
- Cumulative effect of avoidance now puts cut at more than 30%
- Desire on Capitol Hill to fix formula—but how do we pay for it?
What is ASCO Doing?

• Engaging with members of Congress

• Exploring payment reform alternatives to avert SGR cuts for oncology

• Participating in AMA and other specialty society advocacy efforts

• Grassroots activity through ACT Network
Runaway Cost: Whose Fault?

Who's responsible for rising medical costs?

Explore the range of public opinion by selecting a scapegoat.
“Bending the cost curve”... 

Why is oncology a focus?
Costs of Cancer Care Rising Faster than Overall Healthcare

Cumulative % Increase

- Cancer Drugs
- Cancer Medical
- Healthcare
- US GDP
Top Ten Medicare Drugs 2009

- Rituximab cancer treatment: $674
- Ranibizumab: $673
- Bevacizumab injection: $610
- Infliximab injection: $497
- Injection, pegfilgrastin 6mg: $411
- Darbepoetin alfa, non-esrd: $361
- Epoetin alfa, non-esrd: $284
- Oxaliplatin: $258
- Docetaxel: $228
- Pemetrexed injection: $190

Source: Moran Company Analysis of Medicare Physician/Supplier Procedure Summary File, 2009
What We See

PRACTICES

• Increasing difficulty for small independent practices
• Trend toward career shifts
• Practice mergers/consolidation
• Limiting Medicare patients
• Growth in audits/accountability measures by payers

PAYERS & POLICYMAKERS

• Focus on cost
• Demand for quality/evidence based medicine increasing
• Push for efficiencies (e.g., EHR)
• Heavy emphasis on demonstration of new models (e.g., bundling)
• Less sympathy for “oncology is special”
Collected Revenue Per Active Hem/Onc

Revenue/Active Hem Onc

Revenue Mix Jan 08 - Dec 09

- Drugs
- Infusion
- Other

75%
15%
10%

Drugs
Infusion
Other
Is Buy and Bill a Sustainable Model?

- ASP+4% proposed during debt ceiling debate
- Temporarily avoided
- Could be on the table again with SGR and deficit reduction discussions
- Every 1% reduction = ~$155 million/year
- Even without cuts, practices are struggling
So...where do we go from here?
Overall Strategy

- Oppose cuts to ASP with no concurrent policy change
- Monitor/be prepared for ASP to show up again in SGR and budget talks
- Pursue policies that move resources from drugs into patient services
- Bring payment reform proposals to the table
- Understand, anticipate trends
Exploring New Policy

- **Brookings**
  - They have a close working relationship with Congress
  - Congress is asking for their advice/analysis
  - Brookings reaching out to physician specialties for input

- **Analysis of alternatives**
  - Need to test new ideas in diverse practice settings
  - Construct demonstrations
  - Building consensus with wide range of stakeholders
  - Any change will need a reasonable period of transition (3-5 years)
In the Meantime…

• Continued close monitoring to avert “midnight action”

• Continue collaboration with ASP coalition

• Remain engaged with Congress
  – Signals still strong that alternate to buy and bill is a policy goal
  – Retain or even enhance current resources in the system

• Data collection to update understanding of practice distribution and configuration, site of care, workforce, etc.

• Develop proposals for payment reform

• Pursue consensus on proposed model across oncology
Support Legislative Action

- H.R. 905 - Fix to Average Sales Price
- Potential Payment for treatment plan and summary
- Payment for End of Life Counseling

Rep. Lois Capps (D-CA)
Find Acceptable Alternatives

• Episodes of care?
• Bundling?
• Accountable Care Organizations?
• Oncology specific patient centered medical home?
• Increased use of non-physician providers?
• Something else?

New Ideas
Anticipate Trends to Support Practice

*Tracking the Demographics of Oncology*

- How many medical oncologists are there?
- How many practices? How many sites?
- What are the access issues?
- How many solo practitioners are there?
- What percentage of practices are hospital based?
- Referral patterns?
Engage Payers: Provider/Payer Initiative

Constructive dialogue
Innovation
Share issues
Open communication
PPI: Some Agenda Items

- Innovative care and delivery systems
- Coordination of care
- Clinical trial coverage
Quality Oncology Practice Initiative (QOPI™)

• Oncologist-led, practice-based quality improvement program
• Goal is to promote excellence in cancer care by helping practices create a culture of self-examination and improvement
• Includes measurement, feedback and improvement tools for medical oncology practices
• More than 600 practices enrolled
Why is QOPI™ Important?

- **Quality is here to stay**
  - Central to health reform
  - Seen as key to “bending the cost curve”

- **We have a choice**
  - Sit back and allow others to define our quality
  - That will lead to every insurer having a unique program

  **OR,**
  - Create our own; by colleagues for colleagues
  - Convince insurers to use this single standard
But QOPI Has Shortcomings:

• Retrospective
• Data collected only twice per year
• Data reported on only a sample
• Manual review and entry required
• Intensive resource needs = barrier to adoption
QOPI Needs to Evolve to Become:

- Prospective
- Consecutive
- Longitudinal
The Next Major Step

- Helping physicians and patients with increasingly complex information
- Using HIT to ensure data liquidity and knowledge flow
- The time is right for ASCO’s most ambitious quality project
- Creating the Rapid Learning System for Oncology
Health Care Practitioners:

• Real time information to stay current with evolving research, evidence, and guidelines

• Real time decision support tools to make treatment decisions in an increasingly difficult environment

• Real time Quality measures and benchmarking to drive higher quality, lower cost care with better outcomes
Patients:

• To become more informed decision makers and contributors to their own cancer care

• To have the ability to manage adverse events with evidence based options

• To communicate in real time with caregivers and healthcare providers
Payers:

• A way to demonstrate quality and cost-effective care

Researchers:

• To streamline and speed up scientific discovery
• To reduce time to identify key events and make changes
A simple description…

A system in which real-time clinical data is captured, analyzed, and used to enhance patient care and drive scientific discovery
In Providing Care

**TODAY’S CARE MODEL**
- Providers seek out content
- Providers duplicate clinical documentation and data entry
- Care is fragmented and key information is missing
- Research requires years; real-world data are lacking

**TOMORROW’S RLS MODEL**
- Content comes to providers at point of care
- Enter once/use many’ principle maximizes data from routine care
- Data flow across patients and providers
- Learning from every patient becomes a reality; cycle of EBM is dramatically hastened
PARADIGM SHIFT

In Technology

TRADITIONAL REGISTRY
- Requires Query Writers & Analysts
- Form the Query, Get the Data, Use the Data
- Structure Data Only
- Requires Special Skills

TOMORROW’S RLS MODEL
- Ability to Explore Data Freely
- Get All Data, Explore the Data, Apply the Data
- Structured and Non-Structured Data
- Familiar Tools Requiring Minimal Training

ASCO’S RAPID LEARNING SYSTEM
ASCO’S RAPID LEARNING SYSTEM

ASCO’S ONCOLOGY RLS

PATIENT DATA
- Patient reported information

PROVIDER DATA
- Electronic health record
- Practice management system

PATIENT KNOWLEDGE
- Individualized education and decision support
- Real time symptom management
- Treatment plans and summaries
- Treatment calendars
- Social support

PROVIDER KNOWLEDGE
- Next-generation OOPR participation and benchmarking reports
- Clinical guidance/decision support tools
- Meet quality reporting requirements
- Patient treatment plan and treatment summary
- Patient identification for clinical research
- Information exchange with other providers

RESEARCHER DATA
- New evidence
- Guidelines/guidance

RESEARCHER KNOWLEDGE
- Comparative effectiveness research
- Health outcomes studies
- Population health studies
- Clinical trial development
- Evidence generation
ASCO has been in the “quality” business for at least fifteen years. One could argue that the very founding of the Society in 1964, intended to facilitate the exchange of clinical and scientific information, was designed to improve the quality of cancer care.

- Trusted & respected source for oncologists and oncology information
- QOPI®
The ASCO Board of Directors has adopted several guiding principles for RLS:

• Rigorous
• Patient focused
• Transparent
• Independent
• Inclusive
• Streamlined
• Sustainable
The “Choosing Wisely Campaign”

• Proposed by Howard Brody, MD, PhD
  “Medicine's Ethical Responsibility for Health Care Reform — The Top Five List”

• Challenge to medical specialties: Identify five costly practices that are commonly performed and lacking evidence of efficacy
ASCO Participation

• Led by ASCO Cost of Cancer Care Task Force
  – Multidisciplinary group of oncologists

• Chose treatments based on comprehensive review of published studies, guidelines from ASCO and other organizations

• Input from more than 200 oncologists
  – Practicing oncologists
  – State leaders
  – Patient advocates
“Top 5” List for Oncology

*Question these things before doing them:*

1. Use of chemotherapy for patients with advanced cancers who are unlikely to benefit, and who would gain more from a focus on palliative care and symptom management.

2. For early breast cancer, use of advanced imaging technologies (i.e., CT, PET and radionuclide bone scans) in cancer staging.

3. For early prostate cancer, use of advanced imaging technologies (i.e., CT, PET and radionuclide bone scans) in cancer staging.

4. Routine use of advanced imaging and blood biomarker tests for women treated with curative therapy for breast cancer and who have no symptoms of recurrence.

5. Use of white cell stimulating factors for patients who are at low risk for febrile neutropenia.
Research Funding
"I don't think it's reasonable to assume that NIH is going to have another doubling... [of its budget] anytime soon..."

One idea... is whether university faculty members receiving NIH grants should continue to have their salaries largely supported by those grants.”

Francis S. Collins
NIH Director
“At a time of tight budgets with no possibilities for increases in the near future, along with the enormous costs that other diseases are going to place on our healthcare system in the next decade, I believe that the NIH needs to revisit its funding priorities.”

John LaMattina
Retired President of Global R&D
Pfizer
NIH Funding

• 2012
  – NIH = $300 million or 1% increase
  – NCI = $22 million increase

• 2013 – President’s Budget
  – NIH = flat funding
  – NCI = $3 million increase

Flat is the new increase
What ASCO is Doing: Telling Our Story

• Articulating the potential of future research with genomic medicine

• Taking the message to Capitol Hill and regulators with our sister organizations
Equity
Oral Parity

- Patient out of pocket expense for oral chemotherapy often much higher than for IV therapies

- Increasing number of oral drugs in pipeline threatens growing access issue for cancer patients

- Parity bills enacted in 16 states; legislation introduced in 23 states
Potential Issues

- “Parity” could result in IV therapies being subjected to same out of pocket expense as oral
- Bill language varies
- Main concern is patient access
What is ASCO Doing?

• Preparing a guide for state advocates outlining elements that should be addressed in any bill
• Creating fact sheet and talking points
• Providing model bill language
• Explore inclusion of parity language as part of essential health benefits requirements (which has largely been deferred to states)
Evidence Based Advocacy

• There is tremendous scientific progress...and promise of more

• Nowhere is the story more compelling than in cancer, but we must tell it together
Your Washington Team

- 40+ professional staff at ASCO headquarters
  - Research Policy
  - Government Relations
  - Guidelines
  - Practice Management/Policy
  - Health Services
  - Quality

- Polsinelli Shughart law firm
  - Steve Stranne, MD, JD
  - Harry Sporidis

- The Moran Company

- Oncology Metrics

…and several outside law firms/consultants who support us
Become involved in advocating for an environment where all cancer patients have access to the best quality care.

To learn more: visit www.capwiz.com/asco and www.ASCO.org/advocacytools
Working together…

…we will improve care and outcomes for our patients and sustain the practice of oncology for years to come