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Solving the Silent Crisis

Advocacy Strategies to Resolve and Prevent Domestic Drug Shortages

KENYON FARROW
US & GLOBAL HEALTH POLICY DIRECTOR
TREATMENT ACTION GROUP

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The problem

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- U.S. pathway to elimination of TB threatened—decreased funding, increased problems accessing drugs and biologics
- Major obstacles to access: shortages, supply interruptions and cost
- Can lead to:
  - treatment interruptions →resistance, longer periods of infectiousness, missed work
  - suboptimal treatment regimens →more toxicity
  - delays in hiring of health care and other professionals
  - loss of precious time and resources from program side

Table

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Table 1: TB Drug and Biologic Shortages in the U.S. 2011-2013

TB Product	Supplier(s)	Reason(s) for Shortage
Isoniazid	Teva West-Ward (VersaPharm) Sandoz	Lack of raw materials; manufacturing discontinuation; other
Ethambutol	Teva West-Ward (VersaPharm) Lupin	Manufacturing discontinuation
Injectable rifampin	Bedford Pfizer West-Ward (VersaPharm)	Increased demand outpacing supply; other
Capreomycin	Akorn	Manufacturing problems; lack of raw materials; sole-source U.S. manufacturer
Amikacin	Teva Bedford (discontinuing production)	Manufacturing problems; lack of raw materials; increased demand outpacing supply
Streptomycin	X-GEN	Increased demand outpacing supply
Kanamycin	APP Pharmaceuticals	No longer produced in the United States
Clofazimine	Novartis	Problem with API
Tubersol	Sanofi Pasteur	Manufacturing problems

2013 Consultation

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- **A Silent Crisis: Tuberculosis Drug Shortages in the United States** (January 18, 2013 in Washington DC)
- Cosponsored by TAG, the American Thoracic Society, RESULTS, the Center for Global Health Policy, and PATH
- Meeting participants (>60)
  - TB control program managers, researchers
  - FDA, CDC, GDF
  - Supply-chain managers, pharmaceutical reps /manufacturers
  - Advocates, TB survivors
  - Press
- Presentations took place in the morning session, and the afternoon session involved break-out group conversations and a facilitated full-group discussion.

Findings of 2013 consultation

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- Too few API suppliers and manufacturers
- Inadequate interagency communication
- Need for better supply-chain management
- Poor risk-management, both for purchasers (TB programs) through stockpiles and suppliers due to lack of good demand forecasting
- Limited surveillance and tracking around shortages.

http://www.treatmentactiongroup.org/tb/drugs-advocacy/stock-outs/federal-advocacy-meetings/Silent-Crisis

Where are we now?

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- NTCA TB Drugs and Diagnostics Shortages Reporting Mechanism
- CDC examination of several options
- Proposed FDA rule
- Yet, nearly a year later:
  - Still major gaps in improving supply-chain management and demand forecasting
  - Several drugs still have single-source providers (cycloserine, capreomycin, clofazimine)
  - No stable market to attract/retain suppliers
  - Interagency communication still inconsistent
  - Regulatory conditions still challenging for suppliers
  - **Shortages have persisted and possibly worsened**

Jan 15, 2014 Meeting Goals

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- Inter-agency and multi-stakeholder dialogue
- Purpose: examine options to **mitigate** and **prevent** drug and biologic shortages
  - Proposed models are food for thought; not prescriptive
  - Discuss advantages and disadvantages from many perspectives
    - National agencies, state, local, clinician, patient, manufacturer
- Outcomes-driven: focused on identifying potential solutions to take forward
  - Remembering this will be just a first step

2014 Consultation

- **Solving the Crisis: Tuberculosis Drug Shortages in the United States** (January 15, 2014 in Washington DC)
- Cosponsored by TAG, National Tuberculosis Controller's Association (NTCA), and PATH
- Meeting participants (24)
  - TB control program managers, researchers
  - FDA, CDC, GDF, HHS
  - Advocates (TAG, ID Society, RESULTS, PATH, ATS, ASTHO)

Meeting Outline

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- Introductions
- **Morning session:** presentations on models and options to respond to and prevent shortages
- **Afternoon session:** open discussion of disadvantages and advantages presented in am
- Lunch
- Identifying preferred elements/models/options
- Consideration of internal and external needs to facilitate implementation
- Mapping next steps

2014 Findings & Recommendations

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- Create a rotating, vendor-managed inventory reserve
- Centralize procurement
- Expand the pool of U.S. suppliers
- Expand markets to maintain existing U.S. suppliers
- Improve communications

Next Steps

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- Future meetings
- NTCA will translate the global index on pharmaceutical corporate social responsibility into the U.S. setting to create accountability for sponsors of TB drugs
- NTCA and CDC will adapt the GDF's risk schematic to the U.S. setting
- Advocates including IDSA will highlight the repercussions for the economy and jobs that Tubersol shortages caused
- Media/Dissemination

Sources

- Shah N, Barry P, True L, et al. Drug interruptions: a new challenge for treating multidrug-resistant tuberculosis in the United States. Poster session presented at: American Thoracic Society International Conference; 2012 May 18–23; San Francisco, CA.
- Food and Drug Administration (U.S.). Drug Shortages [Internet]. 2013 May 14 (cited 2013 May 14) Available from:http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm314742.htm
- LoBue, Philip (U.S. Centers for Disease Control and Prevention, Division of Tuberculosis Elimination, Atlanta, GA). E-mail communication. 2013 November 14.