



## POLICY RESPONSES TO THE GROWING THREAT OF ANTIBIOTIC RESISTANCE

POLICY BRIEF 4

JANUARY 2008

### LEGISLATIVE ROUNDUP FOR 2007

In 2007 the problem of antibiotic-resistant infections gained ground in the national consciousness and climbed to greater prominence on state and national legislative agendas, for good reason. More people die with methicillin-resistant *Staphylococcus aureus* (MRSA) in the United States than die of AIDS. In 2005, the number of MRSA-related hospitalizations topped 278,000, and it continues to grow.<sup>1,2</sup> Increasing knowledge of the national scope of the problem was dramatized by local reports of young athletes, teachers, and other healthy people succumbing to community-acquired MRSA. Cancelled sporting events and closed schools taught people first hand about the emerging public health threat of antibiotic resistance.

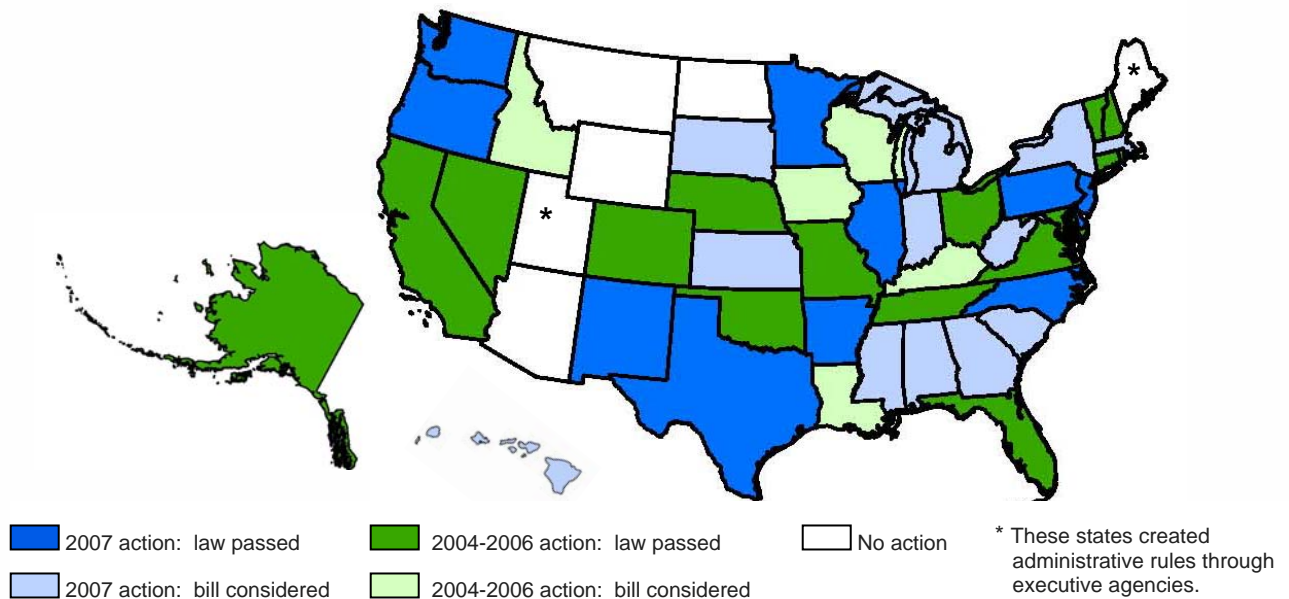
State and national legislators reacted to these events by proposing laws that increase coordination among federal agencies, encourage development

of new antibiotics, and support research initiatives investigating how to slow the rise in antibiotic resistance. Other bills focused on reducing healthcare-associated infections (HAIs), which are mainly spread in hospitals and nursing homes and often are highly antibiotic-resistant. State legislative activity began in 2003, but increased significantly in 2007. The year saw more state bills (many which became law) directed at HAIs and antibiotic resistance than any previous year. A record number of bills was introduced at the federal level in 2007, the first session of the 110th Congress. Nearly all the national bills are still pending.

#### State Legislative Activity

In 2007 laws were passed in 11 of 23 states that considered legislation addressing the rising number of HAIs (see Figure). Nine states established either HAI reporting or infection control requirements. The other two states created committees to investigate the best

**FIGURE:** More states considered HAI legislation in 2007 than the previous three years combined. Over half of the states now have HAI laws (states with action in 2007 and previous years are included in the 2007 groups).



system for HAI reporting, with the goal of implementing such a system in coming years. Another state, Utah, did not pass legislation, but the Department of Health issued an administrative rule requiring hospitals participate in its newly developed HAI surveillance system.

About half of the states now require HAI reporting and a growing number also require hospital infection-control measures.<sup>3</sup> By the end of 2007, only four states—Arizona, Montana, North Dakota, and Wyoming—had not formally considered legislation requiring HAI reporting.<sup>4</sup>

### Federal Legislative Activity

The 110th Congress considered more than three times the number of bills directly addressing antibiotic resistance in its first session than the previous Congress did in both of its sessions combined (see Table). The latest bills also address a broader range of issues related to antibiotic resistance than did earlier proposals, including coordinating federal agencies, encouraging the development of new antibiotics, promoting public education, reporting HAI-related rates, research on the appropriate use of current antibiotics, and preventing the spread of antibiotic-resistant infections in community settings.

Some of the bills create new incentives to encourage research, such as:

- additional funding for National Institutes of Health (NIH) research grants
- funding for Centers for Disease Control and Prevention (CDC) research grants
- tax incentives for drug and vaccine research

Other proposals create incentives to encourage improved hospital infection control through:

- mandatory HAI reporting
- exploring how a grant program or Quality Improvement Payment Plan—sponsored by the Centers for Medicare and Medicaid Services (CMS)—could further reduce HAI rates

Several of the bills also seek to allocate more federal money for other programs designed to slow the spread of antibiotic resistance. These funds would be distributed through CDC programs, the Department of Education, and new organizations established by legislation (see the accompanying table for information on the specific provisions of proposed legislation).

Additionally, the Agency for Healthcare Research and Quality was set to receive \$5 million for MRSA prevention programs in the original Health and Human Services (HHS) appropriations bill vetoed by President Bush, but this did not make it into the omnibus appropriations bill (PL 110-161) that was signed into law in late December 2007.

### FDA Amendments

The only legislation relating to antibiotic resistance that the 110th Congress has passed thus far is the Food and Drug Administration (FDA) Amendments Act of 2007. This law requires the Secretary of HHS to identify and regularly update clinical susceptibility information for common bacteria and antibiotics. This information will be made publicly available so it can guide healthcare providers in wisely using the available drugs.

The 2007 FDA amendments also enacted provisions to encourage the development of new antibiotics. A primary mechanism for spurring this development is the issuance of clinical trial guidelines for new antibiotics seeking FDA approval. These guidelines, which must be reviewed periodically, are intended to reduce the uncertainty associated with antibiotic research and development for pharmaceutical companies. The law also asks the FDA to explore the potential for infections caused by antibiotic-resistant bacteria to qualify for government research grants or contracts under the Orphan Drug Act, which encourages development of drugs for conditions affecting fewer than 200,000 people in the United States.

**TABLE:** Bills Related to Antibiotic Resistance Introduced in the 109th and 110th Congresses

Introduced	Bill #	Short Title	Sponsor (Cosponsors)	Relevant Provisions	Committee/Status
06/30/05	H.R.3154	Infectious Diseases Research and Development Act	Cubin (7)	incentives for drug, vaccine, and diagnostic test R&D	Energy and Commerce Subcommittee on Health
11/16/05	H.R.4349	Patient Safety Act	Hinchey (18)	public HAI reporting	Ways and Means and Energy and Commerce Subcommittee on Health
12/14/05	S.2104	American Center for Cures Act	Lieberman (3)	incentives for drug, vaccine, and diagnostic test R&D	Health, Education, Labor, and Pensions
03/02/06	S.2358	VA Hospital Quality Report Card Act	Obama (0)	public HAI reporting at VA hospitals	Veterans' Affairs
03/02/06	S.2359	Hospital Quality Report Card Act	Obama (0)	public HAI reporting	Finance
02/16/07	H.R.1174	Healthy Hospitals Act	Murphy (42)	requires public HAI reporting and authorizes CMS to explore financial incentives to reduce rates	Ways and Means Subcommittee on Health and Energy and Commerce Subcommittee on Health
02/27/07	S.692	VA Hospital Quality Report Card Act	Obama (1)	see S.2358	Veterans' Affairs
03/09/07	H.R.1448	VA Hospital Quality Report Card Act	Lowey (22)	see S.2358	Veterans' Affairs Subcommittee on Health
03/13/07	H.R.1496	Beating Infections through Research and Development (BIRD) Act	Baird (4)	drug, vaccine, and diagnostic test R&D incentives	Ways and Means, Energy and Commerce Subcommittee on Health, and Judiciary Subcommittee on Courts, the Internet, and Intellectual Property
09/19/07	H.R.3580	Food and Drug Administration Amendments Act	Dingell (2)	incentives for drug R&D	Public Law 110-85
09/27/07	H.R.3697	Strategies to Address Antimicrobial Resistance Act	Matheson (18)	expands CDC education programs; creates Office of Antimicrobial Resistance to coordinate federal action, including collecting data on antibiotic use and resistance	Energy and Commerce Subcommittee on Health
10/25/07	H.R.3964	Healthy Schools Act	Cantor (0)	develop prevention guidelines and surveillance methods for MRSA in schools; grants for school programs	Energy and Commerce Subcommittee on Health
10/31/07	S.2278	Community and Healthcare-Associated Infections Reduction (CHAIR) Act	Durbin (7)	incentives for R&D; public HAI reporting; investigate CMS payment plan to further reduce HAIs	Health, Education, Labor, and Pensions
11/06/07	S.2313	Strategies to Address Antimicrobial Resistance Act	Brown (4)	see H.R.3697	Health, Education, Labor, and Pensions
11/14/07	S.2351	A bill to amend the Internal Revenue Code...	Schumer (1)	incentives for drug, vaccine, and diagnostic test R&D	Finance
11/15/07	H.R.4214	Community and Healthcare-Associated Infections Reduction (CHAIR) Act	Cummings (5)	see S.2278	Energy and Commerce
11/15/07	H.R.4200	A bill to amend the Internal Revenue Code...	Towns (4)	see S.2351	Ways and Means
12/11/07	H.R.4451	MRSA Research and Study Act	Stearns (0)	grants for MRSA research at universities	Energy and Commerce
12/11/07	H.R.4352	To provide \$30,000,000 in funding...	Towns (0)	funds MRSA and other resistant pathogen programs at public schools	Education and Labor and Energy and Commerce
12/19/07	S.2525	MRSA Infection Prevention and Patient Protection Act	Menendez (1)	MRSA screening and isolation in hospitals and public reporting of MRSA rates	Health, Education, Labor, and Pensions
12/19/07	S.2526	Worker Infection Protection Act	Menendez (2)	develop guidelines to protect healthcare workers and first-responders from MRSA	Health, Education, Labor, and Pensions

Note: This list does not include legislation focused on tuberculosis, general patient safety, or antibiotics in the food supply through livestock use. Requests for GAO reports are also not listed.

## Congressional Hearings

On November 7, 2007 the House Oversight and Government Reform Committee held a hearing spearheaded by ranking minority member Rep. Tom Davis (R-VA). Rep. Davis' Virginia district was home to more than 20 suspected MRSA cases in the public school system.

The hearing focused on policy responses to community-associated MRSA, including a national resistance-surveillance system, CDC funding, and vaccine research. Chairman Henry Waxman announced a plan for two follow-up hearings in spring 2008, one to focus on healthcare-associated MRSA and the other on the root causes of emerging antibiotic resistance.<sup>5</sup>

## Other Federal Action

Progress was also made in 2007 toward implementing past legislation. The Deficit Reduction Act of 2005 required CMS to identify preventable medical errors or treatment-associated conditions and to develop a plan for excluding treatment of the resulting conditions from Medicare reimbursement. The Final Rule, published in August 2007, lists three routes of transmission for HAIs for which Medicare will no longer reimburse treatment costs beginning October 2008: catheter-associated urinary tract infections, vascular catheter-associated infections, and surgery site infections following coronary artery-bypass graft surgery. CMS will consider extending the rule in 2009 to include ventilator-associated pneumonia and *Staphylococcus aureus* septicemia. It will also continue to analyze how this policy could be extended to include MRSA and *Clostridium difficile*-associated disease, two common and serious HAIs.<sup>6</sup>

## Expectations for an Active 2008

About half of the states do not yet require HAI reporting, leaving many hospitals without a clear incentive to improve infection control or the accountability needed to verify improvement. States will likely continue to pass HAI laws in 2008, with more requiring infection control plans in addition to infection reporting.

At the national level, most of the introduced bills remain in committee. As the 110th Congress convenes for its second session, at least some are likely to move forward, but which bills, if any, will become law remains uncertain.

## References

1. Klevens, R. M., M. A. Morrison, et al. (2007) "Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States." *Journal of the American Medical Association* 298(15): 1763-1771.
2. Klein, E., D. L. Smith, R. Laxminarayan (2007) "Hospitalizations and deaths caused by methicillin-resistant *Staphylococcus aureus*, United States, 1999-2005." *Emerging Infectious Diseases* 13(12): 1840-1846.
3. RFF (2007). "The States Take Action: Hospital Infection Reporting and Control." [http://www.extendingthecure.org/downloads/Policy\\_Brief2\\_Nov07\\_State\\_Actions.pdf](http://www.extendingthecure.org/downloads/Policy_Brief2_Nov07_State_Actions.pdf) (accessed January 9, 2008).
4. Consumers Union (2007). "Summary of State Activity." [http://www.consumersunion.org/campaigns/learn\\_more\\_background/003544indiv.html](http://www.consumersunion.org/campaigns/learn_more_background/003544indiv.html) (accessed January 9, 2008).
5. Waxman, H. (2007). "Chairman Waxman's Opening Statement." <http://oversight.house.gov/story.asp?ID=1606> (accessed January 16, 2008).
6. CMS (2007). "Hospital-Acquired Conditions." [http://www.cms.hhs.gov/HospitalAcqCond/06\\_Hospital-Acquired%20Conditions.asp](http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired%20Conditions.asp) (accessed January 16, 2008).