AMERICANS' ATTITUDES ABOUT CHANGING CURRENT PRESCRIPTION DRUG & MEDICAL DEVICE REGULATION

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STAT

INTRODUCTION

A new poll of adults in the United States by *Stat* and Harvard T.H. Chan School of Public Health examines public opinion on provisions in the 21st Century Cures Act and a similar package in the Senate, which aim to speed up the process for developing new prescription drugs and medical devices. A majority of Americans do not favor these measures, after being told that changing government regulations could help make new drugs and devices available faster to patients, but could also increase the risk that therapies with harmful side effects or ones that are less effective could be approved for public use. Additionally, most adults do not believe these changes to accelerate the development and review process would lead to lower drug prices for consumers.

Policies that intend to increase competition in the U.S. pharmaceutical market by requiring the Food and Drug Administration (FDA) to reciprocally approve drugs from a list of designated countries, like those included in the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act, were also met with skepticism. More than three in five Americans believe the FDA should conduct its own reviews when considering whether to approve a drug for sale in the U.S. rather than relying on the testing standards of other nations.

21st CENTURY CURES ACT

On July 10, 2015 the U.S. House of Representatives passed H.R.6,[1] a 362-page bill "to accelerate the discovery, development, and delivery of 21st century cures," by a vote of 344 to 77.[2] The 21st Century Cures Act, as it is commonly called, is "a bipartisan bill that would reform the current standards and appropriations for biomedical research, provide $1.75 billion annually for the National Institutes of Health (NIH) and $110 million for the Food and Drug Administration (FDA)."[3]

The bill's authors assert that in addition to substantial funding, collaboration, and operational changes to the NIH and FDA, the bill would improve the ways in which medical therapies are developed, reviewed and approved in order to get better treatments to patients and to do so faster. The Committee on Energy and Commerce describes, HR6 "clears the way to use new and creative adaptive trial designs and deploy the most modern statistical and data tools, while significantly reducing existing, duplicative or unnecessary paperwork requirements" and allows for faster patient recruitment.[4]

Some scientists have pushed back against the bill, however. A June 2015 article in the *New England Journal of Medicine* argued that provisions in the Cures Act would allow the FDA to approve drugs on the basis of less rigorous data and lower scientific standards, provide hospitals with a financial bonus for administering costly but unproven antibiotics, and lighten regulatory standards for safety in addition to

[1] U.S. Senate, H.R. 6, 114th Congress, First Session, "An Act to Accelerate the Discovery, Development, and Delivery of 21st Century Cures, and for Other Purposes," https://www.gpo.gov/fdsys/pkg/BILLS-114hr6rfs/pdf/BILLS-114hr6rfs.pdf.
[2] Govtrack.us, "H.R. 6: 21st Century Cures Act," https://www.govtrack.us/congress/bills/114/hr6.
[3] Govtrack.us, "Summaries for the 21st Century Cures Act," https://www.govtrack.us/congress/bills/114/hr6/summary.
[4] U.S. House of Representatives, Committee on Energy and Commerce, "The 21st Century Cures Act (HR 6)," https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Cures2015FACTSHEET.pdf.

separating those responsibilities from the FDA.[5] Furthermore, the editorial staff of *Nature Medicine* described in October 2015, "The 21st Century Cures Act, if passed, could to lead to an even lower threshold for the approval of high-risk devices."[6]

Despite outspoken resistance from some members of the scientific community, the U.S. Senate began assembling a similar, bipartisan legislative package of its own this year. As of May 8, 2016, the package included 17 bills passed by the committee between February and April. The bundle differs from its companion in the House in some ways, but its overarching goals are similar. Like the House's bill, the Senate's package permits the use of new kinds of data and information during the approval application process to the FDA, including more reliance on post-market surveillance data; allows for smaller, faster clinical studies of antibiotic drugs in certain circumstances; expedites the development and review process for certain medical devices; and increases patient and caregiver feedback in the drug development and review process.

Conversations regarding the 21st Century Cures Act and the Senate bundle have primarily occurred in Congress, academic journals, and industry publications, with little coverage in mass media. This poll aims to illuminate how Americans feel about some of the major changes proposed by these bills which may, in turn, better inform Congress' ongoing deliberations.

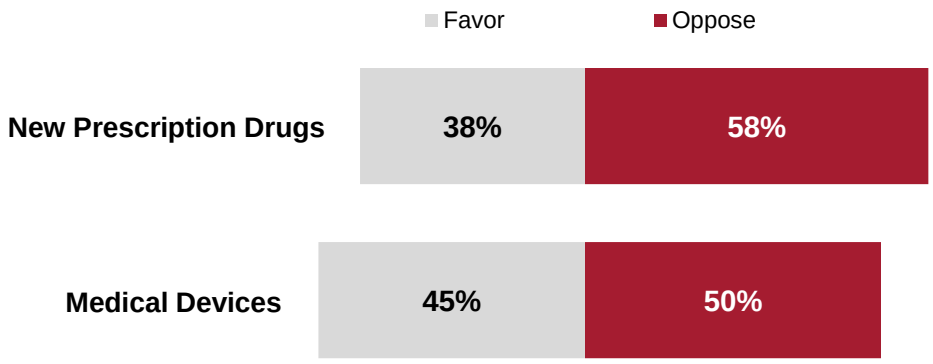
[5] Jerry Avorn and Aaron S. Kesselheim, "The 21st Century Cures Act – Will It Take Us Back in Time?" *New England Journal of Medicine* 2015;372(26):2473-2475, http://www.nejm.org/doi/full/10.1056/NEJMp1506964.
[6] "A Closer Look at the 21st Century Cures Act," *Nature Medicine* 2015;21:1103; published online October 7, 2015, http://www.nature.com/nm/journal/v21/n10/full/nm.3976.html.

FINDINGS

The poll divided participants into two groups: Those who would receive questions about prescription drugs and those who would receive questions about medical devices such as pacemakers, joint replacements and breathing equipment. Adults who were interviewed about prescription drugs were told that it can take about ten years of development, testing and review before **new prescription drugs** meet government safety and effectiveness standards and are made available to the public. The poll went on to explain that some people want to change these government standards to make new drugs available faster, while other say that changing government standards to speed up the process would increase the risk that drugs with harmful side effects or ones that are less effective would be approved for public use.

When asked how they feel about these measures, nearly three in five (58%) adults in the U.S. say they oppose changing government standards to make the process for developing new prescription drugs faster, while less than two in five (38%) favor such changes (*Figure 1*). Men (45%) were more likely than women (32%) to favor changing government standards to make new drugs available faster, as were high-income adults (44%) living in households with annual incomes of at least $75,000, as compared to low-income adults (30%) living in households with annual incomes less than $25,000.

FIGURE 1. Percent of adults in the U.S. who favor or oppose changing government standards to make the process of developing new prescription drugs or medical devices faster.



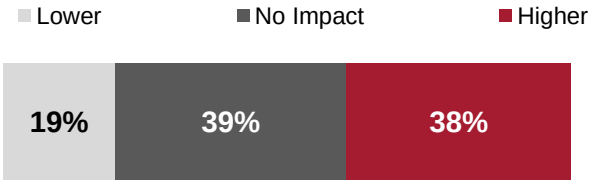
To those adults who were interviewed about medical devices, the poll explained that it can take several years of development, testing and review before **medical devices** such as pacemakers, joint replacements and breathing equipment meet government safety and effectiveness standards and are made available to the public. It went on to detail that some people want to change government standards to make new devices available faster; even if that means later recalling products for harmful side effects after some people have been hurt. Others, meanwhile, say government standards should remain as they are to ensure the safety and effectiveness of new devices, even if that means many people who need them must wait longer.

When asked how they feel about these measures, one half (50%) of adults in the U.S. say they oppose changing government standards to make the process for developing medical devices faster, while 45 percent favor such changes (*Figure 1*). Men (54%) were more likely than women (36%) to want to speed up the process, as were Republicans (58%), compared to Democrats (38%).

IMPACT ON PRICE

The poll followed-up with those interviewed about prescription drugs and asked whether they thought speeding up the development process would influence the **price of new prescription drugs**. Nearly two in five (39%) Americans believe that changing government standards to speed up the development, testing and review of new prescription drugs would *not* have much of an impact on the price of new drugs (*Figure 2*). About the same proportion ─ 38 percent ─ believe it would make the price of new drugs higher. In contrast, less than one in five (19%) adults in the U.S. believes speeding up the drug development process would lower the price of new pharmaceuticals.

FIGURE 2. Percent of adults in the U.S. who believe that changing government standards to speed up the development, testing and review of new prescription drugs would make the price of those drugs higher or lower, and those who believe it would not have much of an impact.



The poll also asked whether or not Americans believe the **FDA should consider price when making its decision to approve a drug**. It explained that the FDA works to protect people's health by making sure new drugs are safe and effective before they are approved for use and that it does not currently consider price when making these decisions. Participants were then asked if they believe the FDA should be allowed to deny approval to a drug if the agency decides the price is too high, or whether they believe this is *not* something the FDA should be allowed to do.

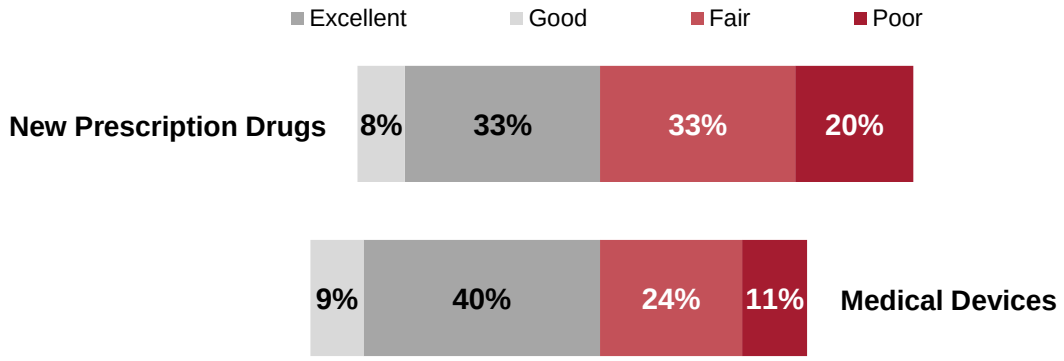
Nearly one-half (49%) of Americans say the FDA should *not* be allowed to deny approval to a drug if the agency decides the price is too high, while more than two in five (44%) believe this is something the FDA should be allowed to do.

PERCEPTIONS OF THE FOOD & DRUG ADMINISTRATION

To obtain a baseline for how the public feels the FDA's current functioning, poll participants were asked **how well the FDA regulates new prescription drugs**. A majority (53%) of adults in the U.S. say the agency does a fair or poor job of regulating the safety and effectiveness of new pharmaceuticals (*Figure 3*). In contrast, about one third (33%) believe the FDA does a good job, while less than one in ten (8%) say it does an excellent job.

Adults ages 18-29 (52%) were significantly more likely than adults over age 50 (33%) to say the agency does an excellent or good job.

FIGURE 3. Percent of adults in the U.S. who believe the FDA does an excellent job, good job, fair job, or poor job of regulating the safety and effectiveness of new drugs and medical devices such as pacemakers, joint replacements, and breathing equipment.



Similarly, when asked **how well the FDA currently regulates medical devices** such as pacemakers, joint replacements, and breathing equipment, Americans were much more positive. Nearly half (49%) of adults in the U.S. say the FDA does a good or excellent job of regulating the safety and effectiveness of medical devices, while more than a third (35%) say the agency does a fair or poor job (*Figure 3*). Self-identified Democrats (52%) were significantly more likely than Republicans (36%) to say the FDA does an excellent or good job of regulating medical devices.

These results echo findings from a November 2014 Gallup poll, which asked participants to rate the job being done by the FDA. More than half (53%) of adults said the FDA was doing a fair or poor job, while 45 percent said the agency was doing a good or excellent job.[7]

APPROVING DRUGS FROM OTHER COUNTRIES

Separate from the 21st Century Cures Act, a recent bill in the Senate, S. 2388, the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act, proposed requiring the FDA to approve drugs from other countries for sale in the U.S. as a way to increase competition in the American pharmaceutical market and promote access to needed medical therapies. [8] According to a press release from one of the bill's co-sponsors,[9] it instructs the Secretary of Health and Human Services to approve a drug, device or biologic if the FDA confirms the product is "lawfully approved for sale in one of the listed countries, not a banned device by current FDA standards, and there is a public health or unmet medical need for the product."

[7] Jeffrey M. Jones, "Americans' Ratings of CDC Down After Ebola Crisis," Gallup Poll, November 20, 2014, http://www.gallup.com/poll/179522/americans-ratings-cdc-down-ebola-crisis.aspx.
[8] U.S. Senate, S. 2388, 114th Congress, First Session, "A Bill to Amend the Federal Food, Drug, and Cosmetic Act to Provide for Reciprocal Marketing Approval of Certain Drugs, Biological Products, and Devices That Are Authorized to be Lawfully Marketed Abroad, and for Other Purposes," https://www.congress.gov/114/bills/s2388/BILLS-114s2388is.xml.
[9] U.S. Senator for Texas Ted Cruz, "Cruz, Lee Introduce RESULT Act," December 11, 2015, http://www.cruz.senate.gov/?p=press_release&id=2554.

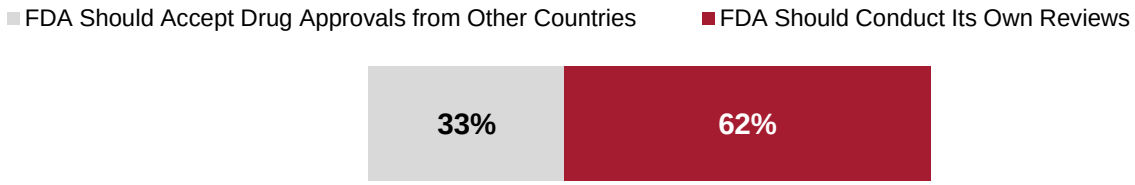
The listed countries to which the RESULT Act refers are included in Section 802(b)(1) of the FDA Export Reform and Enhancement Act of 1996:[10]

> *"Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa or any member nation in the European Union or European Economic Area. As of July 2007, the EU countries are: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The number of 'listed countries' expands automatically as countries become members of the EU or EEA."*

In an effort to gauge public opinion on **regulatory changes proposed in the RESULT Act**, the poll asked whether the FDA should be required to approve prescription drugs and medical devices for unmet medical need in the U.S. that have already been approved by developed countries with different standards such as the U.K., Canada, Romania and Japan, or whether the FDA should conduct its own review when deciding whether these products should be available in the U.S.

More than three in five (62%) Americans say the FDA should do its own reviews of products before they become available in the U.S., while a third (33%) of adults say the FDA should be required to approve products from countries included in the RESULT Act (*Figure 4*). Self-identified Republicans (44%) were more likely than Democrats (29%) to support approving drugs and devices from other countries.

FIGURE 4. Percent of adults in the U.S. who either believe (A) the FDA should be required to approve prescription drugs and medical devices for unmet medical needs in the U.S. that have already been approved by developed countries with different standards such as the UK, Canada, Romania and Japan or (B) the FDA should conduct its own reviews when deciding whether such drugs should be available in the U.S.



DRUG SIDE EFFECTS

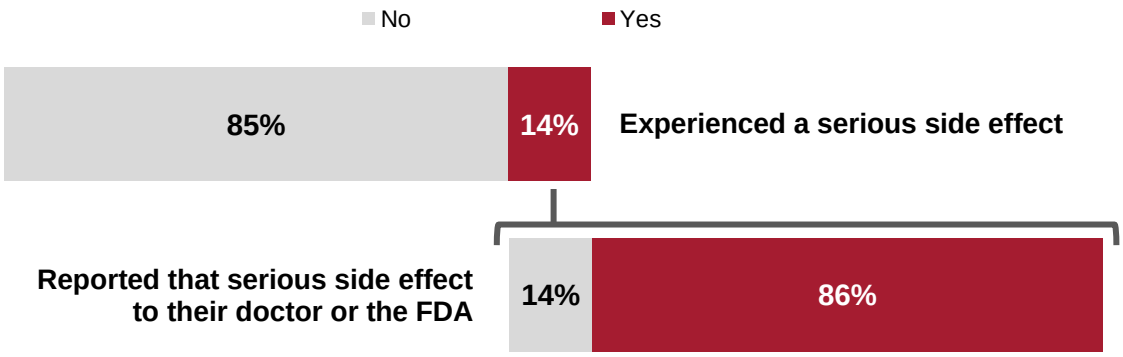
Critics of the 21st Century Cures Act and its companion package in the Senate contend that lowering the threshold for approving medical devices and drugs would increase the need for a reliable, accurate and

[10] U.S. Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996," July 23, 2007, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125799.

timely post-market surveillance system to monitor adverse side effects and recall products, when necessary.[11] To gauge the prevalence of serious side effects resulting from prescription drugs and patient compliance with reporting measures, which forms the backbone of post-market surveillance systems, the poll asked whether, in the past five years, participants had experienced any **serious side effects as a result of taking prescription drugs**. One in seven (14%) American adults say they have (*Figure 5*). Women (19%) are significantly more likely than men (9%) to report having experienced serious side effects as a result of prescription drugs in the past five years, as are low-income adults (21%) living in households with annual incomes of less than $25,000, as compared to high-income adults (13%) living in households with annual incomes of at least $75,000.

Among those who say they *did* experience a serious side effect, 86 percent say they reported their experience to a doctor or the FDA; however, one in seven (14%) adults says they did not report these problems.

FIGURE 5. Percent of adults in the U.S. who have or have not experienced a serious side effect as a result of taking prescription drugs in the past five years. Among those who *have* experienced one or more serious side effects, the percent who say they did or did not report those side effects to their doctor or the FDA.



PRESCRIPTION DRUG ADVERTISING

On November 17, 2015 the American Medical Association (AMA) called for a ban on direct-to-consumer advertising of prescription drugs and medical devices, including television advertisements.[12] According to a statement released by the group, member physicians are concerned about "a growing proliferation of ads is driving demand for expensive treatments despite the clinical effectiveness of less costly alternatives."

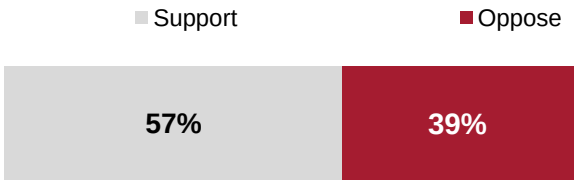
In order to gauge public opinion on these potential reforms, the poll explained that some people believe pharmaceutical companies should no longer be allowed to advertise prescription drugs on television because ads sometimes encourage patients to ask for costlier drugs that may not be appropriate for them

[11] "A Closer Look at the 21st Century Cures Act," *Nature Medicine* 2015;21:1103; published online October 7, 2015, http://www.nature.com/nm/journal/v21/n10/full/nm.3976.html.
[12] American Medical Association, "AMA Calls for Ban on Direct to Consumer Advertising of Prescription Drugs and Medical Devices," November 17, 2015, http://www.ama-assn.org/ama/pub/news/news/2015/2015-11-17-ban-consumer-prescription-drug-advertising.page.

and because marketing costs increase drug prices. On the other hand, the poll described that some believe television ads make patients more informed about their treatment options.

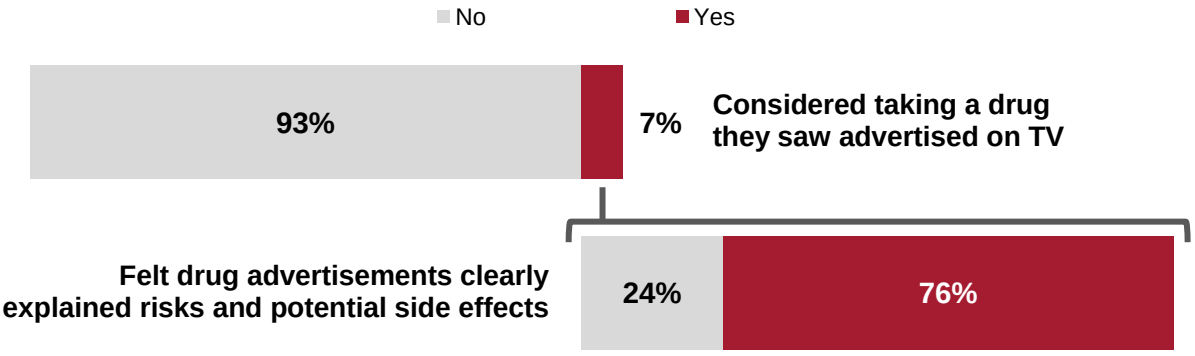
About three in five (57%) adults in the U.S. say they **support removing prescription drug advertisements from television**, while less than two in five (39%) say they oppose this change (*Figure 6*). There were no significant differences in opinion on this question by party, income, or sex.

FIGURE 6. Percent of adults in the U.S. support or oppose removing prescription drug advertisements from television.



The poll also asked about **Americans' personal experiences with drug advertisements on television**. Just 7 percent of adults in the U.S. say they have considered taking a prescription drug they saw advertised on television in the past 12 months, while more than nine in ten (93%) say they have not considered taking an advertised drug (*Figure 7*). Among those who say they have considered taking a drug they saw advertised on TV, more than three-quarters (76%) of adults say the advertisements they saw clearly told them what they needed to know about the possible risks or side effects the might experience if they were to take the drug. Just under one-quarter (24%) say the advertisements they saw did not clearly explain these risks and side effects.

FIGURE 7. Percent of adults in the U.S. who have or have not considered taking any prescription drugs they saw advertised on television in the past 12 months. Among those who *have* considered taking a drug they saw advertised on television, the percent who say the advertisements they saw clearly told them what they needed to know about the possible risks or side effect they might experience if they were to take the drug.



METHODOLOGY

This poll was conducted by *Stat* and Harvard T.H. Chan School of Public Health. Representatives of the two organizations worked closely to develop the survey questionnaire and analyze the results of the poll. *Stat* and Harvard T.H. Chan School of Public Health paid for the survey and related expenses.

The project team was led by Robert J. Blendon, Sc.D., Richard L. Menschel Professor of Health Policy and Political Analysis at Harvard T.H. Chan School of Public Health, and Gideon Gil, Managing Editor, Enterprise and Partnerships of *Stat*. Harvard research team also included John M. Benson, Caitlin L. McMurtry, and Justin M. Sayde.

Interviews were conducted with a nationally representative sample of 1,006 randomly selected adults, ages 18 and older, via telephone (including cell phones and landlines) by SSRS of Media, Pennsylvania. Interviews were conducted in English and Spanish. The interviewing period was April 27 - May 1, 2016. The data were weighted to reflect the demographics of the national adult population as described by the U.S. Census.

When interpreting these findings, one should recognize that all surveys are subject to sampling error. Results may differ from what would be obtained if the whole U.S. adult population had been interviewed. The margin of error is ±3.6 percentage points for the full sample of respondents. For questions asked of half-samples, the margin of error is approximately ±5.1 percentage points.

Possible sources of non-sampling error include non-response bias, as well as question wording and ordering effects. Non-response in telephone surveys produces some known biases in survey-derived estimates because participation tends to vary for different subgroups of the population. To compensate for these known biases and for variations in probability of selection within and across households, sample data are weighted by household size, cell phone/landline use and demographics (sex, age, race/ethnicity, education, and region) to reflect the true population. Other techniques, including random-digit dialing, replicate subsamples, and systematic respondent selection within households, are used to ensure that the sample is representative.

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STAT/Harvard T.H. Chan School of Public Health Poll

Americans' Attitudes about Changing Current Prescription Drug and Medical Device Regulation

This survey was conducted for *STAT* and Harvard T.H. Chan School of Public Health via telephone by SSRS, an independent research company. Interviews were conducted via telephone (cell phone and landline) April 27 – May 1, 2016, among a nationally representative sample of 1,006 U.S. adults. The margin of error for total respondents is +/- 3.6 percentage points at the 95% confidence level. For questions asked of half-samples, the margin of error is approximately +/- 5.1 percentage points. More information about SSRS can be obtained by visiting www.ssrs.com

I'd like to ask you some questions about the Food and Drug Administration, also called the FDA…

(Asked of half-sample A; n = 501)

ST-01. Would you say the FDA does an excellent job, a good job, only a fair job, or a poor job of regulating the safety and effectiveness of new prescription drugs?

An excellent job	A good job	Only a fair job	A poor job	Don't know/ Refused
8	33	33	20	6

(Asked of half-sample B; n = 505)

ST-02. Would you say the FDA does an excellent job, a good job, only a fair job, or a poor job of regulating the safety and effectiveness of medical devices such as pacemakers, joint replacements, and breathing equipment?

An excellent job	A good job	Only a fair job	A poor job	Don't know/ Refused
9	40	24	11	16

(Asked of half-sample A; n = 501)

ST-03. It can take about ten years of development, testing and review before new prescription drugs meet government safety and effectiveness standards and are made available to the public. Some people want to change these government standards to make new drugs available faster. Others say that changing government standards to speed up the process would increase the risk that drugs with harmful side effects or ones that are less effective would be approved for public use. Do you favor or oppose changing government standards to make the process for developing new drugs faster?

Favor	Oppose	Don't know/ Refused
38	58	4

(Asked of half-sample B; n = 505)

ST-04. It can take several years of development, testing and review before medical devices such as pacemakers, joint replacements and breathing equipment meet government safety and effectiveness standards and are made available to the public. Some people want to change government standards to make new devices available faster; even if that means later recalling products for harmful side effects after some people have been hurt. Others say government standards should remain as they are to ensure the safety and effectiveness of new devices, even if that means many people who need them must wait longer. Do you favor or oppose changing government standards to make the process for developing medical devices faster?

Favor	Oppose	Don't know/ Refused
45	50	5

(Asked of half-sample A; n = 501)

ST-05. If government standards were changed to speed up the development, testing and review of new prescription drugs, do you believe it would make the price of those drugs higher, lower, or do you think it would not have much of an impact on the price of new drugs?

Higher	Lower	Would not have much impact	Don't know/ Refused
38	19	39	4

(Asked of half-sample B; n = 505)

ST-06. Should the FDA be required to approve prescription drugs and medical devices for unmet medical needs in the U.S. that have already been approved by developed countries with different standards such as the UK, Canada, Romania and Japan? Or should the FDA do its own reviews when deciding whether these drugs should be available in the U.S.?

FDA should be required to approve prescription drugs and medical devices for unmet needs in the U.S. that have already been approved by developed countries with different standards	FDA should do its own reviews	Don't know/ Refused
33	62	5

(Asked of half-sample C; n = 511)

ST-07. The FDA works to protect people's health by making sure new drugs are safe and effective before they are approved for use. It does not currently consider price when making its decisions. Do you believe the FDA should be allowed to *NOT* approve a new drug if it decides the price is too high, or do you believe this is not something the FDA should be allowed to do?

FDA should be allowed to <u>NOT</u> approve a new drug if it decides the price is too high	This is not something FDA should be allowed to do	Don't know/ Refused
44	49	7

(Asked of total sample; n = 1006)

ST-08. Have you experienced any serious side effects as a result of taking prescription drugs in the past five years?

Yes	No	Don't know/ Refused
14	85	1

(Asked of those who experienced side effects as a result of taking prescription drugs in the past five years; n = 160)

ST-09. Did you report those serious side effects to your doctor or the FDA, or not?

Yes	No	Don't know/ Refused
86	14	--

(Asked of total sample; n = 1006)

ST-10. In the past 12 months, have you considered taking any prescription drugs you saw advertised on television?

Yes	No	Don't know/ Refused
7	93	*

(Asked of those who have considered taking prescription drugs they saw advertised on TV in the past 12 months; n = 84)

ST-11. Thinking about the most recent drug you considered taking, did the advertisements you saw clearly tell you what you needed to know about the possible risks or side effects that you might experience if you were to take the drug, or did they not?

Yes	No	Don't know/ Refused
76	24	*

(Asked of half-sample D; n = 495)

ST-12. Some people believe that pharmaceutical companies should no longer be allowed to advertise prescription drugs on television because ads sometimes encourage patients to ask for costlier drugs that may not be appropriate for them and because marketing costs increase drug prices. Others believe television ads make patients more informed about their treatment options. Do you support or oppose removing prescription drugs advertisements from television?

Support	Oppose	Don't know/ Refused
57	39	4