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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
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June 14, 2024

Dr. Jeff Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

Thank you for appearing before the Subcommittee on Health on Wednesday, May 22, 2024, to testify at the hearing entitled "Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, July 31, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Cathy McMorris Rodgers

1. What will it take to fill the open roles for review staff and related administrative staff at FDA?

    a. What efforts are under way to attract talent and hire these critical roles?

2. The FDA along with many other federal agencies instituted virtual work policies during the COVID-19 pandemic. There have been concerns that the ongoing virtual schedule has impacted the frequency and quality of interactions between the FDA and important stakeholders. Does the FDA plan to bring staff back to in-person work and meetings with sponsors and patients?

3. The Committee understands that the term "telework" refers to a work flexibility arrangement that allows an employee to work from an approved alternative worksite other than the employee's official duty location for an approved number of days each pay period. Within each center, what percentage of employees telework?

    a. What is the range of approved numbers of days each work period?

    b. What is the most typical number of approved numbers of days each work period?

    c. How is the specified number of days enforced?

    d. Within each center, what percentage of employees are fully remote?

    e. Can FDA provide a summary of actions it is taking to increase the frequency and quality of interactions with sponsors?

4. The Food and Drug Administration (FDA) has proposed a new rule, Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes, which would require reclassification of certain wound products containing antimicrobials or other chemicals. This proposed re-classification would fundamentally change the regulatory status of both future and existing wound care products by making them subject to 510(k) requirements with special controls or premarket approval (PMA), regardless of how long they have been on the market. The FDA has cited concerns that these products are potentially increasing human antimicrobial resistance (AMR) as the reason for this reclassification. Please explain the scientific evidence that supports FDA's belief that certain relevant products are contributing to AMR.

5. Assuming there is evidence that certain wound care products are contributing to AMR, how will reclassifying these products prevent patients from developing antimicrobial resistance?

6. How does the FDA intend to take patient access into consideration when it comes to reclassification?

The Honorable Robert Latta

1. Due to the difficulty conducting facility inspections of medical device manufacturers in China, is examining products at ports of entry the best way to inspect and detain products with registration and quality issues?

    a. Please explain the manner in which the agency scrutinizes imports from China.

    b. Can the agency exert additional pressure and focus on manufacturers with past citations?

    c. What additional resources are needed to improve the vigilance over Chinese medical device imports?

2. This Committee has been looking into the visibility of the medical device supply chain, especially as supply chain vulnerabilities came to light during the PHE. FDA requires medical devices to be marked with a unique device identifier (UDI) to assist with tracking, tracing and recalls. Please tell us whether FDA is planning to update its regulations, so all medical device sizes are following UDI requirement?

3. The Centers for Medicare and Medicaid Services (CMS) has become increasingly interested in collecting more evidence and information about certain drugs, devices, and technologies before making them widely available to Medicare beneficiaries despite the fact that these therapies already have received approval or clearance from the Food and Drug Administration (FDA). For example, CMS effectively restricted patient access to treatment only within the context of additional clinical trials approved by CMS in the Coverage with Evidence Development (CED) National Coverage Determination (NCD) for Alzheimer's Disease drugs. In other cases, CMS has declined to cover routine clinical trial costs for therapies under investigation for new indications despite the existence of the longstanding policy (NCD 310.1) requiring Medicare coverage for routine costs of clinical trials. In other words, a growing number of administrative actions suggest that CMS is seeking to expand its role and make clinical and scientific decisions historically under the strict authority of the FDA. Given this trend, is the FDA concerned that CMS has exceeded its administrative authority in taking these administrative actions?

    - Link: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2

    a. Does the FDA have suggestions for ensuring that Medicare beneficiaries have appropriate access to drugs, devices and technologies that have received FDA approval or clearance?

b. How does the FDA view its work with CMS moving forward?

c. Does the FDA expect to collaborate more broadly CMS on making clinical and scientific determinations that historically the FDA has made on its own? If yes, please describe how the FDA envisions enhanced collaboration with CMS and how such collaboration will ensure patient access to medically necessary and life-saving therapies.

4. Laboratories have long filled the gap in pediatric testing because many FDA-authorized IVDs are not cleared or approved for use in pediatric patients, and modifications may be necessary to suit the pediatric population. However, I've heard concerns that the final rule will limit the availability of tests for our nation's youngest patients because such modifications would require FDA clearance or approval. Please explain how the final rule will not alter the availability of tests for pediatric patients.

The Honorable Gus Bilirakis

1. In January 2024, CDRH announced its intent to reclassify (down-classify) most Class III IVDs to Class II. Additionally, CDRH's 2014-2015 Strategic Priorities included a review of device types subject to a PMA to determine if they are appropriate for a premarket or postmarket data shift or reclassification. Can you provide an update on this activity?

    a. Does FDA have a designated criteria for down-class?

    b. How are staff being trained on this process

    c. What is the schedule/sequence of events? What is the immediate next step?

2. The FDA's final rule related to lab-developed tests (LDTs) includes enforcement discretion related to tests offered by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. Rare disease patients often face a strenuous journey to achieve an accurate diagnosis. Studies indicate this can take seven years or more. Access to LDTs is often a key component of receiving an accurate diagnosis for rare disease patients, so it is critical stakeholders understand the "unmet need" enforcement discretion contained in the final rule. When do you anticipate the FDA issuing additional guidance related to the "unmet need" enforcement discretion contained in the LDT final rule?

    a. What factors will you be considering?

The Honorable Earl "Buddy" Carter

1. How is the FDA planning on enforcing the rule regarding Laboratory Developed Tests in rural communities where these hospitals and labs won't be able to afford to meet the regulatory requirements put forth by the FDA?

a. What are the estimated annual costs required to implement this rule, both in terms of costs to U.S. taxpayers and also higher patient health care costs for lab tests?

2. FDA appears to have departed from the preamble in the final rule outlining the requirements for 361 HCT/P classification, in which FDA stated that cutting, grinding, and shaping of HCT/Ps constitute minimal manipulation. (See 66 Fed. Reg. 5447, 5447) How does FDA approach "minimally manipulated" standard in human bone powder versus other types of human tissue manufactured in powder form (e.g., dermis, amniotic membrane, placental disc)?'

3. From each of your respective standpoints, what are the criteria applied by the Device Center and the Biologic Center to determine whether product powdered wound dressing derived solely from human tissue should be classified as a device versus a biologic?

    a. Please explain how you apply these criteria to powdered wound dressing and other types of human tissue products that fall short of 361 HCT/P classification due to more than minimal manipulation.

The Honorable Neal Dunn, M.D.

1. I appreciate FDA's response to a recent bipartisan letter from me and several other members on the use of cloud services by regulated industry, including drug and medical device companies. As FDA has indicated, cloud services offer benefits—including enabling product sponsors to use the most advanced analytic and AI tools to support innovation. Are entities regulated by your center able to use cloud services?

    a. And what steps do you plan to take to train FDA reviewers and investigators on the ability for cloud services to support product quality, facilitate innovation, and meet compliance requirements?

The Honorable Dan Crenshaw

1. Most clinical laboratories have limited or no experience working with the FDA or with FDA expectations. Laboratories will need help interpreting FDA expectations, sooner rather than later. What is the Agency's plan for rapidly publishing guidance documents to help laboratories understand the requirements?

2. Most clinical laboratories have limited or no experience working with the FDA or with FDA expectations. FDA has several webinars scheduled over the next few months, but what other efforts are the Agency pursuing to quickly educate clinical laboratories on these expectations, and how laboratories can comply in a manner that does not interrupt or interfere with the critical patient care they provide?

The Honorable Troy Balderson

1. Strict security requirements result in a restricted pool of vendors who can provide FISMA approved solutions. This smaller pool of vendors means higher costs for products and services as the FDA has less negotiation power during the selection phase. This limits the overall technical innovation due to lower variety in solution selection. How does FDA plan to effectively balance the need for stringent security requirements and meeting the PDUFA VII commitments?

    a. Can you elaborate on FDA's plans to put out an RFP for third-party vendors?

    b. What is the projected timing?

2. PDUFA VII states that, within 6 months of completion of a demonstration project, the FDA must compile a summary of outcomes and next steps and share with industry at the regularly scheduled FDA-industry meetings. What measures will FDA put in place to encourage engagement and feedback from industry?

    a. What can industry expect after the demonstration projects have concluded?

3. Are there barriers that are delaying or impacting FDA's ability to formally select additional demonstration projects for the regulatory information exchange reforms?

    a. Does FDA plan to engage going forward with Industry on demonstration project selection?

4. Nearly 5 years after Congress passed the 2017 FDA Reauthorization Act, which included a provision mandating that FDA establish rules for the sale of over-the-counter hearing aids, the rule finally became effective in October 2022. With this new category, we are seeing an increase of new market participants. With more pathways for individuals with hearing loss to access hearing aids, it is crucial that we ensure companies operating in this space are playing by the rules and that FDA is exercising its appropriate oversight and enforcement authority to ensure the safety and efficacy of these medical devices. To that end, multiple issues have been identified with the potential to create greater consumer confusion or, worse, place consumers at an increased safety risk.

    a. Is FDA aware of bad actors that are advertising and selling OTC hearing aids?

        - Let me provide some examples:

            - Improper classification/registration/listing issues:
                - Individual devices are not listed at all or have been listed under different names than they are being sold as;
                - Companies using "self-fitting" terminology when not listed under the correct product code classification
                - Primary manufacturers offering private label products to a variety of companies may be registered and products listed, but

many of the sellers are not registered and/or listed. This makes it difficult for consumers to find products on the FDA database and violates registration/listing requirements.

- Advertising and claims issues:
  - Companies using the FDA logo on their website to imply endorsement or approval of devices
  - Companies advertising OTC devices as appropriate for "mild to severe hearing loss"
  - Companies claiming devices can "restore natural hearing" (which no company can claim)
  - Companies claiming to be the "top-seller for prominent hospitals and clinics globally"

b. Has FDA received reports or complaints of violations of OTC regulations?

c. Is FDA taking or has FDA taken any actions to monitor or ensure compliance with applicable regulations?

d. Has FDA taken action against bad actors in the OTC hearing aid space either based on submitted complaints or on its own?

e. What specific actions has FDA taken on its own, or in conjunction with FTC, to address regulatory violations relating to OTC hearing aids?

f. State attorneys general have been at the forefront of issue consumer warnings and even taking action against bad actors. Is FDA aware of these efforts and/or working with state authorities where appropriate?

g. Is the FDA coordinating with any other federal agency (FTC, FCC) to enhance consumer knowledge of the OTC market?

h. Are there jurisdictional gaps that need to be addressed through legislation or other pathways between FDA and FTC?

i. Who is regulating or can regulate false or misleading information on the internet?

j. False and misleading information is most robust on internet platforms, do you have a plan to address these issues?

k. What is the breakdown between domestic and foreign manufacturers in the OTC hearing aid market in the U.S.?

l. Is there any type of verification that these companies and their products are being manufactured, sold, or distributed in compliance with applicable regulations?

m. Are you concerned with reports of "fly by night" companies that pop up, sell products backed by returns or warranties, that close up shop suddenly, leaving consumers without recourse?

The Honorable Dianna Harshbarger

1. We continue to face a devastating opioid and substance use disorder crisis in this country. Deadly new synthetics are hitting the street constantly and must be tracked so that doctors and other caregivers can best understand how to care for those struggling with substance use disorder. Laboratory developed testing (LDT) services play a critical role in testing for such substances because they can be developed and deployed to respond to the rapidly changing illicit drug market. However, I'm concerned that the LDT final rule will slow the availability of new diagnostic tests and hamper our nation's ability to respond to this public health crisis. Can you explain how the final rule will affect the availability of tests to detect new and rapidly changing illicit drugs?

2. Agency data show that the FDA completed "zero" inspections of Chinese device manufacturers in 2022. Meanwhile, the FDA completed 1,706 inspections of domestic device manufacturers that same year. Substandard Chinese medical devices are flooding the U.S. market and threatening domestic producers that are held to a higher standard. We must ensure that foreign manufacturers are held to the same standard as domestic manufacturers, to avoid putting our domestic workers and factories at a disadvantage.

    a. How are Chinese medical products allowed to make their way into the U.S. and to patients if the FDA isn't able to inspect the foreign facilities they were manufactured in?

    b. And what steps is the FDA taking to increase the number of foreign inspections overall, and if inspections cannot be done over a reasonable timeframe, what additional steps will FDA take to ensure patients are not at risk?

The Honorable Mariannette Miller-Meeks, M.D.

1. FDA has issued guidance which narrows a bipartisan 21st Century Cures act provision exempting clinical decision support from FDA regulation. As part of the guidance, FDA said that when decision support runs in time sensitive situations, the exemption should not apply because the physicians won't thoughtfully consider the pro's and con's of the recommendation and will just do what it says. Almost everything that happens in a hospital is time sensitive. By including this concept of automation bias, aren't you basically gutting this congressionally mandated exemption?

    a. Doctors are trained to make fast decisions in time sensitive situations. As someone who was a practicing physician for decades, I understand this firsthand. By not giving physicians credit for their ability to think and act quickly, isn't FDA moving into regulating the practice of medicine?

b. Using existing authorities and funding levels, how does FDA intend to regulate the hundreds of thousands of advisories that run throughout the country?

c. Are you concerned that FDA is overextending itself?

2. Dr. Shuren, as we are discussing how the United States can continue to lead in the development of cutting-edge biomedical innovations, we must address the supply chain that moves medications and health supplies from manufacturers to the patients in need. Third-party logistics providers (3PLs) play a key role in the reliability of medical supply chains by moving healthcare goods safely and quickly across the country, often with temperature and time restrictions. To ensure healthcare goods are moved safely, Congress passed the Drug Supply Chain Security Act (DSCSA) in 2013, requiring the FDA to create national standards for the licensure of 3PLs. However, to date final regulations have yet to be released. Can you share insight into when the FDA expects to finalize the pending third-party logistics providers regulations?

3. Dr. Shuren, I am particularly interested in antimicrobial resistance. I would appreciate your thoughts on the importance of clinicians having accurate and readily available diagnostic tools to guide their prescribing decisions and foster antimicrobial stewardship. In 2020, FDA began allowing antimicrobial susceptibility test (AST) manufacturers to use preapproved change protocols for previously cleared ASTs to make breakpoint changes as organisms develop resistance to an antibiotic. This has allowed laboratories to update their AST systems more quickly which is critical for appropriate antimicrobial stewardship. Beyond the use of these types of protocols for existing ASTs, how can CDRH expedite access to new ASTs?

4. Does FDA currently require developers to submit a 510(k) for each and every new drug/bug combination and, if so, are there ways to expedite review of these types of tests based on previous data and the agency's experience in reviewing the hundreds of previously cleared 510(k)'s for other drug/bug combinations?

The Honorable Ann Kuster

1. Current law recognizes that device labeling, including directions for use, may be provided electronically for a wide range of devices—including all prescription devices for use in health care facilities or by health care professionals, as well as other in vitro diagnostic devices for use by health care professionals or in blood establishments. Since Congress last addressed device electronic labeling in 2024, reliance on online information has expanded astronomically. Consumers and patients, as well as health care professionals, increasingly turn to electronic sources for information about products. Electronic labeling provides for rapid, even real-time, updates to labeling, such as clarifications to warnings or other notices. Patients, physicians, caregivers, and manufacturers may all benefit from the broader application of electronic labeling for medical devices. Benefits to device users may include increased availability, utility, interactivity, and accessibility to the instructions for use.

Last year, the Energy & Commerce Health Subcommittee held a hearing on Public Health Security Threat Preparedness, during which I had the opportunity to ask Commissioner Califf a question about medical device labeling and the benefits of moving towards electronic labeling. His response was that he is very much in favor of moving in this direction, with caveats such as ensuring that patients who want or need paper copies can access them. I have joined with my colleagues on this Subcommittee – Representatives Obernolte, Craig, and Crenshaw – to introduce H.R. 3723, the Medical Device Electronic Labeling Act, which will help ensure that patients, physicians, and other users have rapid access to the most up-to-date device information. Dr. Shuren, do you commit to working with us to see this important modernization effort finalized?

The Honorable Kim Schrier

1. I want to follow up on a question I asked about children's access to needed laboratory tests. As I said during the hearing, I have some concerns about the impact of the final LDT rule on children's timely access to needed pediatric tests, given the impact of rare diseases on children's long-term health and wellbeing. In particular, for some pediatric LDTs, there may be only one or two centers worldwide that have the expertise to perform and oversee those tests, given the specialized nature of pediatric health care. Therefore, it's not uncommon for one children's hospital to send a sample to another children's hospital that is not in the same hospital system because that children's hospital has an LDT that can test for a child's particular rare condition. For example, Seattle Children's has the unique challenge of serving very sick children from the surrounding four-state region. There are situations where a hospital in Alaska, which is not a part of the Seattle Children's Hospital system, will send a sample from a child who is need of a diagnostic test that only Seattle Children's can run. This helps ensure a timely diagnosis and prevents the whole family from having to travel to Seattle for the test. Under the final rule, would these situations be considered an "unmet need" even though the test is not developed or used in the same hospital system?

    a. If not, how does FDA plan to ensure that children with rare diseases have access to these types of tests?

The Honorable Diana DeGette

1. In the final Medical Devices; Laboratory-Developed Tests rule, FDA included several categories of tests for which it would continue to exercise targeted enforcement discretion. However, the scope of the enforcement discretion is unclear to many stakeholders. When will FDA provide additional guidance on the circumstances under which it will exercise enforcement discretion?

2. Can FDA provide a specific definition for 1) "unmet need" and 2) when an available test would sufficiently meet the needs of a patient?

The Honorable Jan Schakowsky

1. Dr. Shuren, I am very concerned that the FDA doesn't have enough authority to recall faulty medical devices. On May 8th, the FDA recalled an insulin pump phone application by Tandem Diabetes Care. A software glitch caused the insulin pump to shut down, injuring more than 200 diabetes patients. The FDA must protect patients from faulty devices. However, due to its limited authority, the FDA cannot always demand that companies remove a faulty product from their shelves. What can Congress do to make FDA's recall authority more effective?

2. Dr. Shuren, I am also concerned that hospitalized patients are in danger. Hospitals are supposed to be notified about recalls from manufacturers. These notices are communicated by mail, which can take weeks or months. As a result, patients are notified too late and are at risk of serious injuries or deaths. My bill, the Medical Device Recall Improvement Act, would require the FDA to create an electronic format for recall notifications so patients can receive timely information. How would an electronic format improve the recall notification process and further protect patients?