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February 24, 2022

The Honorable Nancy Pelosi
Speaker of the House
United States House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
Washington, D.C. 20515

RE: Comments Regarding H.R. 6000 — the Cures 2.0 Act

Dear Speaker Pelosi and Minority Leader McCarthy:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully submits the following comments regarding H.R. 6000, the Cures 2.0 Act.

Although Public Citizen supports many of the provisions included in H.R. 6000, we find four sections of the legislation to be objectionable and urge you to oppose the legislation unless those sections are excluded or substantially revised. We also offer recommendations for additional provisions to improve patient safety.

Objectionable provisions

We oppose inclusion of the following provisions of H.R. 6000 and urge that they be excluded or substantially revised:

- *Section 105. Developing antimicrobial innovations:* This section would provide $11 billion to establish a new subscription contract program for certain antibiotics. Unfortunately, this model would be unlikely to spur development of truly innovative drugs to combat infections resistant to current treatments. The subscription-model approach in this section would promote overuse of antibiotics that would be better preserved and only used when existing antibiotics fail. A subscription model is not suitable for critical-need antibiotics because unlike hepatitis C treatments, there is not urgent unmet need driven by high prices domestically, and there may not be competing therapies that are clinically substitutable. Further, eligibility for the program would be poorly targeted through inclusion of products that receive the overly broad Qualifying Infectious Disease Product designation.

- *Section 304. Increasing use of real world evidence:* This section would further erode the Food and Drug Administration's (FDA's) evidentiary standards for ensuring that new drugs are safe and effective by opening the door to greater FDA reliance on evidence from observational studies that are less rigorous than randomized, controlled clinical trials to establish the safety and effectiveness of the new drugs approved under the breakthrough-therapy, fast-track, or accelerated-approval pathways. Evidence from observational studies may supplement but must not supplant data from well-designed,

randomized, controlled clinical trials as the primary evidence for establishing that a drug is safe and effective.

- *Section 309. Post-approval study requirements for accelerated approval:* This section would substantially weaken the FDA's post-approval study requirements for new drugs approved under the accelerated-approval pathway by allowing the FDA to rely on analyses of clinical care data repositories, patient registries, and other sources of real-world evidence — rather than well-designed, randomized, controlled clinical trials — to confirm that drugs approved under this regulatory pathway based on their effect on a surrogate endpoint have an effect on irreversible morbidity or mortality or other clinical benefit. Post-approval studies to establish the clinical benefit of a new drug approved under the accelerated-approval pathway should be limited to well-designed, randomized, controlled clinical trials.

- *Section 404. Coverage and payment for breakthrough devices under the Medicare program:* This section would eviscerate the Centers for Medicare and Medicaid Services' (CMS') reasonable-and-necessary standard for Medicare coverage of breakthrough medical devices by automatically deeming such devices approved or cleared by the FDA on or after March 15, 2021, as reasonable and necessary under the Medicare program. Given the current dangerously low standards for FDA approval or clearance of medical devices, approval or clearance of a breakthrough device should not be automatically deemed to be reasonable and necessary for the purposes of Medicare coverage. CMS, as the steward of two-thirds of the U.S. health care coverage system, should conduct its own independent review of the evidence supporting the safety and effectiveness of such devices and follow its usual procedures for determining whether such devices are reasonable and necessary.

Recommendations to include additional provisions

We urge you to consider expanding H.R. 6000 to include the following provisions to improve patient safety and expand access to medicines by lowering prescription-drug prices:

- *Faster safety updates for generic-drug product labeling*

  Since 1985, generic drug sales have grown dramatically. Approximately 90% of prescriptions now are filled with generic versions, and many drugs are sold only as generics. New safety issues commonly arise after generic versions have entered the market, underscoring the imperative of maintaining incentives for robust manufacturer surveillance of safety concerns throughout the life of a drug product.

  The Food and Drug Administration (FDA) currently does not allow generic drug manufacturers to initiate safety updates to product labeling when they become aware of new risks, although brand-name manufacturers have long had that ability and responsibility. Although the FDA in 2013 proposed a new rule to correct this safety gap,[1] the rule was not finalized and was later withdrawn in 2018.

[1] 78 FR 67985.

Public Citizen urges you to include in H.R. 6000 a provision requiring the FDA to repropose, not later than three months after the date of enactment of the legislation, and promptly finalize, not later than 12 months after the date of enactment of the legislation, a rule allowing generic-drug manufacturers to update product labeling promptly to reflect certain types of newly acquired information related to drug safety, irrespective of whether the revised labeling differs from that of the reference-listed drug, in advance of the FDA's review of the changes through a "changes being effected" (CBE–0) supplement.

- *Restore the right of patients to sue for injuries caused by defective high-risk medical devices*

  A Supreme Court decision in 2008, *Riegel v. Medtronic*, held that the existing law preempts the right of patients to bring damages claims against medical device manufacturers for injuries caused by high-risk medical devices marketed pursuant to a premarket approval application. This decision ended an over 30-year period in which federal and state laws had worked hand in hand to strengthen device safety. Several bills have been introduced to override the *Riegel* ruling over the past several years, including Ariel Grace's Law (H.R. 5403), which was introduced by Rep. Michael Fitzpatrick in 2016 in response to injuries linked to the Essure female-sterilization device.

  Public Citizen urges you to include in H.R. 6000 a provision restoring the ability of patients injured by high-risk medical devices to bring state-law damages actions against device manufacturers. (See Appendix A for suggested statutory text.)

- *Provide the FDA with mandatory drug-recall authority*

  The FDA can require manufacturers to recall medical devices, biological products, controlled substances, tobacco, infant formula, and food. Yet shockingly, when it comes to drugs that are not controlled substances, the FDA can only ask drug producers to issue recalls voluntarily. Over the past decade, there have been numerous examples of drug producers — including traditional compounding pharmacies, outsourcing facilities engaged in the production of sterile compounded drugs, manufacturers of over-the-counter drugs, and manufacturers of homeopathic drug products — disregarding FDA requests for voluntary recalls of tainted or potentially tainted drug products that posed a serious threat to the health of patients and consumers. The Protecting Americans from Unsafe Drugs Act, which was introduced in February by Rep. Andy Kim and passed by the House as part of the America COMPETES Act of 2022 (H.R. 4521), would close this dangerous loophole by granting the FDA mandatory recall authority for all drugs.

  In the event the Protecting Americans from Unsafe Drugs Act is not enacted as part of the America COMPETES Act of 2022, Public Citizen urges you to include such a provision in H.R. 6000.

- *Improve the utility of the National Practitioner Data Bank to better protect patients from dangerous doctors, dentists, and other health care practitioners*

  The National Practitioner Data Bank (NPDB) was authorized by the Health Care Quality Improvement Act of 1986 and began operation on September 1, 1990, after publication of implementing regulations and creation of the NPDB's computer system. The NPDB plays a central role in ensuring patient safety by providing the most comprehensive, reliable information concerning the malpractice-payment and disciplinary history of physicians, dentists, and other health care practitioners to licensing boards, credentialing authorities, peer reviewers, and other users. The purpose of the NPDB is to reduce the likelihood that doctors and other health care practitioners disciplined by state licensing boards, hospitals, or other health care organizations might continue to injure patients by relocating to another state or hospital where their reputations and track records are unknown.

  We have two suggestions for important improvements to the NPDB.

  First, state licensing boards can query the NPDB for the doctors and dentists to whom they have granted licensure or who are applying for licensure. Currently, the cost of performing a one-time query for each query submitted is $2.50. Similarly, the cost of a one-year "Continuous Query" per practitioner is $2.50. Enrollment in Continuous Query allows a state licensing board to be notified by email within 24 hours of any new report received by the NPDB regarding a licensed practitioner.

  However, because of the query cost, most state medical boards do not routinely query the NPDB either on an ad hoc basis or by enrollment in Continuous Query.

  Making NPDB Continuous Query free for all state licensing boards and requiring all states to participate in this service would result in state licensing boards always having the most up-to-date information that is needed to protect the public from dangerous or miscreant practitioners.

  The NPDB also would benefit by being able to compile a single unified list of all practitioners and where they are licensed to practice based on the Continuous Query registration information received from the states.

  Public Citizen urges you to include in H.R. 6000 a provision eliminating all fees for state licensing board enrollment in NPDB Continuous Query and requiring all state licensing boards to enroll in this service.

  Second, among the events that must be reported to the NPDB are malpractice payments made on behalf of individual practitioners. But the current NPDB regulations allow for what is commonly referred to as the "corporate shield" loophole. Use of this loophole involves a practice where a medical-malpractice victim agrees to dismiss a defendant health care practitioner from a malpractice lawsuit or claim — usually as part of settlement negotiations — thereby leaving or substituting a hospital or other corporate entity as a defendant. Such dismissals often occur in response to a request from attorneys of a self-insured hospital or other corporate entity that employs the defendant health care

practitioner. The loophole is used, at least in part, for the purpose of allowing the practitioner to avoid having a report of a malpractice payment made on his or her behalf submitted to the NPDB.

The Health Resources and Services Administration (HRSA) — the agency that operates the NPDB — itself noted in a December 24, 1998, proposed rule intended to close the corporate shield loophole that the loophole "makes it possible for practitioners whose negligent or substandard care has resulted in compensable injury to patients to evade having that fact appear in the [NPDB]." That proposed rule was subsequently withdrawn a year later.

Evidence suggests that the corporate shield loophole is used more frequently today than it was in 1998, when HRSA first sought to close the loophole. Since then, the percentage of physicians who are employed by hospitals and other corporate entities (as opposed to those who are in private practice) has increased markedly.[2] Therefore, the number of doctors who are potentially shielded from reporting by the loophole has increased. Meanwhile, the number of malpractice payments made on behalf of physicians reported to the NPDB has steadily fallen. Although tort reform has played a role in this decline, use of the corporate shield loophole also has contributed to this trend. The result has been a reduction in the comprehensiveness of malpractice-payment data reported to the NPDB and therefore in the usefulness of the NPDB.

Public Citizen urges you to include in H.R. 6000 a provision eliminating the "corporate shield" loophole in the requirement for reporting of medical-malpractice payments made on behalf of practitioners to the NPDB. This could be accomplished most effectively by requiring revisions to the Department of Health and Human Services regulations at 45 C.F.R. § 60.7. (See Appendix B for suggested regulatory revisions.)

Thank you for considering our views on this important legislation.

Sincerely,

Michael Carome, M.D.
Director
Public Citizen's Health Research Group

cc: Members of the following U.S. House of Representatives committees:
Agriculture Committee
Armed Services Committee
Committee on Energy and Commerce
Committee on Homeland Security

[2] http://www.amednews.com/article/20121119/business/311199971/2/.

Committee on Science, Space, and Technology
Committee on the Budget
Committee on the Judiciary
Committee on Veterans' Affairs
Education and Labor Committee
Natural Resources Committee
Ways and Means Committee

Appendix A

The Medical Device Safety Act of 2017

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. SHORT TITLE.

This Act may be cited as the "The Medical Device Safety Act of 2017."

SEC. 2. LIABILITY UNDER STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES.

(a) AMENDMENT.—Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by adding at the end the following:

"(c) NO EFFECT ON LIABILITY UNDER STATE LAW.—Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.".

(b) EFFECTIVE DATE; APPLICABILITY.—The amendment made by subsection (a) shall—

(1) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94–295); and

(2) apply to any civil action pending or filed on or after the date of enactment of this Act.

Appendix B

Proposed Revisions to Department of Health and Human Services regulations at 45 C.F.R. § 60.7 that Would Close the "Corporate Shield" Loophole[3]

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement (or partial settlement) of, or in satisfaction ~~in whole or in part~~ of a ~~claim or a~~ judgment ~~against such physician, dentist, or other health care practitioner for~~ in~~,~~ a medical malpractice~~, must~~ action or claim shall report information respecting the payment and circumstances thereof, as set forth in paragraph (b) of this section, to the Data Bank and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a "payment" and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the physician, dentist, or other health care practitioner for whose benefit the payment is made, including each practitioner whose acts or omissions were the basis of the action or claim— …

[3] Proposed additions are underlined, and proposed deletions are in strikeout.